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AWARD NUMBER: W81XWH-07-2-0080

TITLE: A National Model for Diabetes Prevention and Treatment Program in Civilian and Military Healthcare Beneficiary Populations

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REPORT DATE: March 2010

TYPE OF REPORT: **Final Report**

PREPARED FOR: U.S. Army Medical Research and Material Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

☒ Approved for public release; distribution unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
01-03-2010	Final Report	20 Sep 2007-18 Dec 2009

4. TITLE AND SUBTITLE
A National Model for Diabetes Prevention and Treatment Program in Civilian and Military Healthcare Beneficiary Populations

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-07-2-0080

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Barbara Barnes, M.D.; Linda Siminerio, PhD
Jodi Krall, PhD

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of Pittsburgh Medical Center

Pittsburgh, Pennsylvania 15213

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Material Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)
USAMRAA and AF/SGRM

11. SPONSORING/MONITORING AGENCY REPORT NUMBER

12. DISTRIBUTION AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Reduction in the incidence of diabetes and alleviation of its complications has become a national public health priority The University of Pittsburgh Medical Center, in partnership with the United States Air Force, sought to determine the best methods for preventing diabetes and improving diabetes care. We hypothesized that evidence-based pediatric and adult primary prevention and management programs would reduce risk for diabetes and its complications in civilian and military populations. For these respective populations, we (1) delivered a comprehensive 5-year strategic plan (2) implemented a primary prevention and management system for childhood obesity; (3) implemented primary prevention by disseminating the modified Diabetes Prevention Program strategies through different modalities; (4) implemented diabetes programs based on the Chronic Care Model and (5) investigated and evaluated implementation of glycemic management protocols inpatient setting. A multifaceted approach was used with a comprehensive analysis plan.

15. SUBJECT TERMS: Diabetes, Obesity, Prevention, Treatment, Cost-effectiveness, Chronic Care Model

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b.ABSTRACT	c. THIS PAGE	UU	240	USAMRMC
u	u	u			19b. TELEPHONE NUMBER (*Include area code)*

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INTRODUCTION

In recognition that reduction in the incidence of diabetes and alleviation of its complications have become national public health priorities, the University of Pittsburgh Medical Center (UPMC), in partnership with the United States Air Force (USAF), sought to determine the best methods for preventing diabetes and improving diabetes care in both the civilian and military populations. The purpose of this initiative was to develop primary prevention and diabetes treatment strategies in both adult and pediatric populations and deploy these systems and strategies within a comprehensive model to reduce risk for diabetes and its complications in urban/rural civilian and AF healthcare beneficiary populations. The scope of this initiative spanned the following programmatic and research areas; corresponding goals are listed according to the proposal:

Strategic Plan:

- Development of a 5-year strategic plan to establish and implement a comprehensive prevention and management system for diabetes care and its antecedent conditions

Pediatrics:

- Implementation of primary prevention and management system for childhood obesity
- Advancement of long-term research efforts related to pathophysiological, lifestyle, and behavioral determinants of childhood obesity

Adult:

- Implementation of primary prevention efforts through a variety of modalities to service urban/rural communities.
- Implementation of primary prevention efforts through a variety of modalities to service AF healthcare beneficiary populations.
- Implementation of all elements of the chronic care model for diabetes in urban/rural communities.
- Implementation of all elements of the chronic care model for diabetes in AF healthcare beneficiary populations.
- Implementation of inpatient glycemic management protocols at Wilford Hall Medical Center (WHMC) and investigation and evaluation of these protocols

The purpose of this report is to describe research accomplishments associated with completion of the initiative.

BODY

1. STRATEGIC PLAN

Development of a 5-year strategic plan to establish and implement a comprehensive prevention and management system for diabetes care and its antecedent conditions

UPMC, in coordination with the USAF, developed a comprehensive strategic plan that defines primary prevention and diabetes treatment programs for children and adults that can be deployed in civilian and military populations. The strategic plan serves as a living document that identifies barriers and opportunities within the aforementioned populations. It describes comprehensive, sustainable and reproducible strategies that can be adapted to the needs of specific communities. Through the course of the funding cycle we continued to meet with our USAF partners to review strategies and processes within the strategic plan.

See *Appendix A: Strategic Plan*

2. PEDIATRICS

Pediatric obesity is a public health concern. Prevalence of childhood overweight and obesity among children and adolescents has doubled in the past two decades (1). Obese weight status in childhood is associated with metabolic conditions and health problems, including insulin insensitivity, high blood pressure, and type II diabetes (T2DM)(2). The probability of childhood obesity persisting into adulthood is estimated to increase from approximately 20% at 4 years of age to approximately 80% by adolescence (3). It is probable that co-morbidities will persist in adulthood as well (4).

Obesity and its related health complications put a significant burden on the health care system. The economic cost of childhood obesity-associated illnesses has increased from 35 to 127 million dollars in the last two decades (5). Based on current trends, the prevalence of pediatric obesity will double by 2030 (6). It is estimated that health care costs attributable to obesity will exceed 860 billion dollars, accounting for 16% of total US health care costs (6).

Pediatric obesity is also a concern to the military. The obesity epidemic is likely to affect the military most immediately as a result of increasing the need for dependent care for overweight and obese children. Based on retrospective chart review of 3,406 patients aged 2 to 23 years, we found that 28% or approximately 10,000 of the 35,000 children and youth in the San Antonio AF healthcare beneficiary population are overweight or obese. In addition, an increasing number of recruits do not meet with weight-for-height standards set by the military (7, 8). Furthermore, children of military personnel are more likely in the future to join the armed forces than children in the civilian population (9). Thus, understanding childhood obesity and related conditions among children of military families will likely contribute to improving or maintaining the health of future recruits.

Diabetes Prevention and Weight Management Programs

To address the issue of pediatric obesity in civilian and military populations, Children's Hospital of Pittsburgh of UPMC (CHP) and Wilford Hall Medical Center (WHMC) established a partnership and implemented an evidenced-based model for weight management. The mission of the weight management program is to help children and adolescents achieve and maintain a healthy weight and to prevent, identify and treat weight related problems, such as diabetes, high blood pressure and high cholesterol. The program utilizes family-based behavioral lifestyle intervention, counseling, and goal-setting strategies to implement therapeutic lifestyle changes in children and their families and serves as a hub-site for childhood obesity research studies, including the Research Registry.

Civilian Populations

The objective of this goal was to implement pediatric diabetes prevention and weight management programs through the Healthy Lifestyles Program (HLP) to service urban and rural communities in Southwestern Pennsylvania (SWP). In this report, we describe the implementation and outcomes of three arms of HLP:

1. Healthy Eating Routines and Optimal Exercising Styles (HEROES) program, a peer group intervention
2. HLP clinical assessments, conducted at the CHP Weight Management and Wellness Center (WMWC) and community-based pediatric practices
3. Healthy Behaviors for Life (HB4Life) program, an integrated weight management Web portal

HEROES

HEROES is a group intervention that assists children and adolescents in achieving a healthier lifestyle through peer interaction. The HEROES program was developed by a team of health professionals from the WMWC of CHP. HEROES developers designed the program by comparing nationally recognized pediatric obesity group interventions from psychologist Dr. Leonard Epstein, King's Daughter Health System, All Children's Hospital, Lucille Packard Children's Hospital, Nationwide Children's Hospital, and Kidshape. Program indicators considered "essential" or "best practices" were incorporated into the HEROES program. Table 1 lists indicators and comparative information that guided HEROES design and a description of how these indicators were incorporated into the HEROES program.

Table 1. Program Indicators Incorporated into the HEROES Program

Indicator	Comparative Information	Implementation of Indicators into the HEROES Program
• Program Length	A 12-session program is considered an optimal program length	The HEROES program was conducted based on the 12-session model. Sessions were held once a week for 12 weeks; each session lasted 1.5 hours.
• Staffing	Appropriate staffing, including dietitians/nutritionists and psychologists/behavior therapists, is critical to program success.	A team of four staff members, including a nutritionist and behavior therapist, was determined to be efficacious for delivering the material and managing the logistics of data collection.
• Behavioral Approach	Behavioral change approaches (versus educational models) are required to encourage participants to adopt and sustain healthy lifestyles that support weight management.	The HEROES program was designed to empower participants and their caregivers to choose healthier behaviors. Trained interventionists delivered messages by employing cognitive behavioral therapy and motivational interviewing – two robust methods of behavior change. During sessions, interventionists, participants, and caregivers explored a variety of structured topics such as weight management, nutrition, physical activity, self esteem, and body image.
• Participation Incentive	Providing participants an incentive, such as charging a fee, to participate in the program helps ensure subject retention.	Small prizes were given at the end of the intervention to participants who completed the program. In addition, weekly feedback on weight change progress through a computer model was added to provide further participation incentive.
• Caregiver Participation	Participation of caregivers in group sessions is encouraged to foster behavior change.	Originally, caregivers were encouraged to participate in group sessions. However, parent participation was equal or less than child participation, with an average of two parents participating per session. Those parents that participated also had children that consistently came to the sessions. As such, caregiver involvement, although minimal, did appear to foster child participation. Thus, parental involvement was made a program requirement.

Methods

Testing of the revised HEROES program with 5 groups from March 2005 to June 2008 identified challenges in retaining a significant number of participants in the intervention. The average retention rate of the 5 interventions was 26%. In order to increase participant compliance and, in turn, improve program outcomes, we modified recruitment, screening, and other program aspects through an iterative process in 5 additional groups from July 2008 to August 2009.

These interventions were held at 3 community YMCAs (Pittsburgh, Greensburg, and Sewickley, PA) and a Jewish Community Center in Squirrel Hill, an urban community in Pittsburgh. Two separate groups were conducted at the latter site; one with children and one with adolescents.

Following is a description how recruitment, screening, and other program aspects were refined across the interventions.

Group 1

- Recruitment – The program was advertised through flyers posted at the YMCA and participants recruited by YMCA staff. This recruitment process seemed to cause confusion among parents, such that they were unaware that they were expected to participate in the intervention with their children.
- Screening – There was a large variability in the overweight status of the adolescents. Participants expressed a wide range of body mass index percentiles, categorized as normal to obese status. Extreme variation in weight status, particularly inclusion of adolescents of normal weight, may have negatively influenced the motivation of overweight and obese adolescents to sustain their participation in the program.

Based on outcomes from Group 1, HEROES investigators restructured recruitment and screening procedures. They also decided to build in mechanisms to improve retention for future HEROES interventions. Revised or new procedures were tested with the second group and are described below.

Group 2

- Recruitment – The program was advertised on site (i.e., at YMCA facilities) through flyers and by word of mouth. Names and contact information for interested participants and their parents were given to the HEROES staff. A staff member called parents to invite them and their children to participate in the program. The recruitment call included a more thorough description of the program as well as expectations of program participation.
- Screening – In order to participate in the HEROES program, adolescents were required to have a body mass index at or above the 90th percentile (indicative of overweight/obese weight status). HEROES staff assessed height and weight (to calculate body mass index) as part of a screening process. In addition, adolescents completed a questionnaire that assessed interest and motivation in the intervention program.
- Weekly follow-up telephone calls – HEROES staff called participants once a week for the length of the program to inquire on how the participants were implementing information learned during the program, answer questions and remind participants and their parents of the upcoming intervention session. The telephone calls were designed to support the participants through the behavior modification process and provide accountability to them and their parents for program participation.

Groups 3-5

The recruitment and screening procedures and follow-up mechanisms applied to the 2nd group were also applied to the three remaining interventions. In addition to these procedures, three other mechanisms were included to increase participant motivation and compliance:

- HEROES investigators decided to limit enrollment by gender. HEROES investigators thought that having both genders present at the program might be influencing participants' interest in active program engagement. For example, females might have felt intimidated discussing weight issues in front of their male counterparts.
- Parental participation was made a requirement.
- Weight was assessed for both participants and parents at the beginning of each session. Weight and height (the latter measured at the first and last sessions) were used to calculate BMI. BMI was charted on a computer and the

participant and parent were able to track their weight change as the intervention progressed. This also allowed HEROES staff to provide immediate feedback to participants and discuss concerns or barriers with participants and parents on a regular basis.

Findings

Weight status of patients and parents participating in the 5 interventions occurring from July 2008 to August 2009 was assessed. A total of 111 participants, including 60 children and adolescents and 51 parents, completed the redesigned HEROES intervention during this time period.

Weight significantly decreased from the first to last session (p=0.003) for the total group of participants. Sixty-five percent of participants lost weight, including 58% of youth and 73% of parents (Figure 1). For youth, the average weight loss was 0.53 ± 4.6 lbs (0.21 ± 3.0 % total body weight); maximum weight loss was 11.6 lbs or 6.6% body weight. For parents, the average weight loss was 2.7 ± 6.3 lbs (1.4 ± 3.0% total body weight); maximum weight loss was 23.8 lbs or 12.6% total body weight.

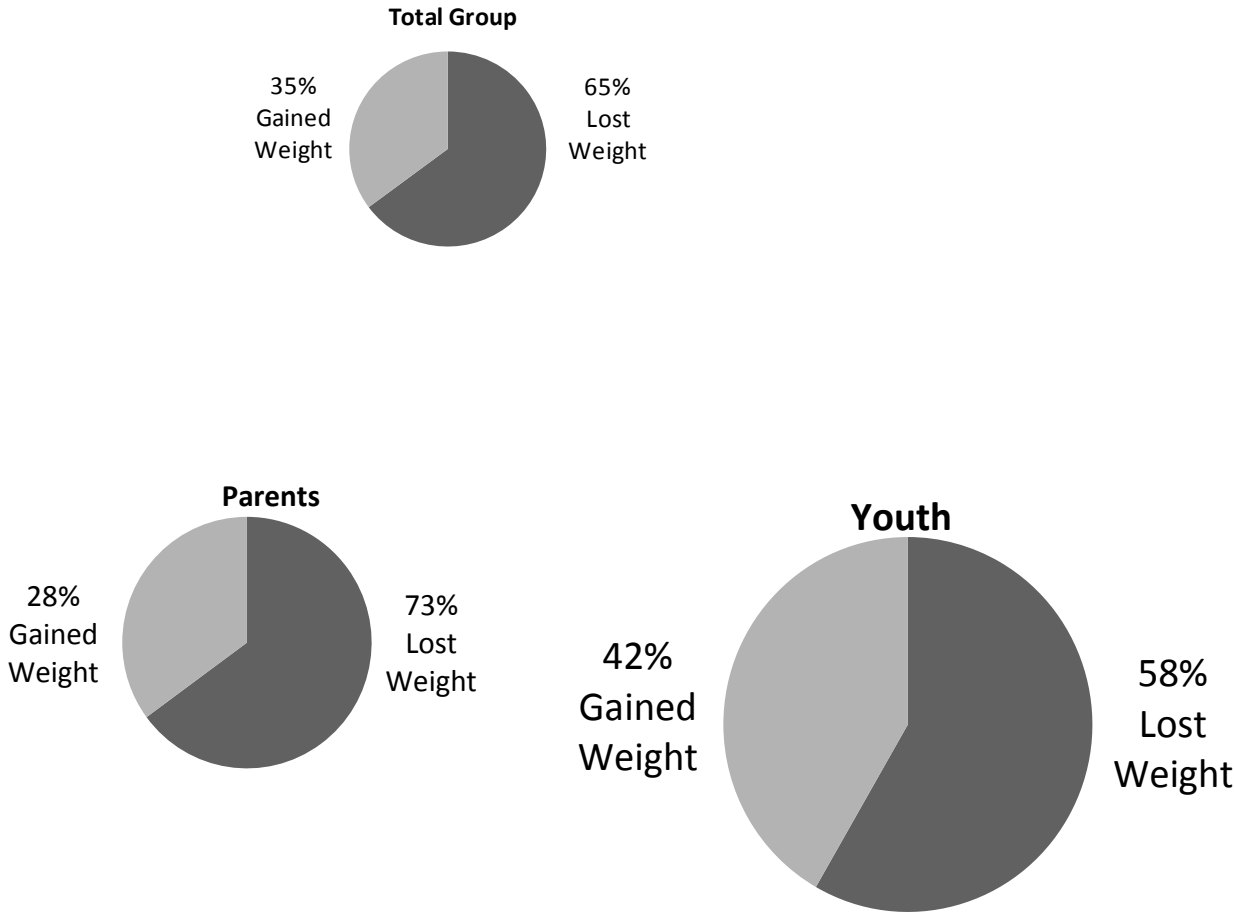


Figure 1. Weight Change for HEROES Participants

Summary

Program investigators utilized nationally recognized programs, participant feedback and program experiences to refine the HEROES intervention through an iterative process. The outcomes of each testing site informed implementation methods of the following program. As demonstrated by program results, refinement strategies appeared to positively influence program effectiveness. Participant and parental compliance improved and a significant proportion of participants decreased their weight while participating in HEROES. Weight significantly decreased from the first to last session for the total group with 65% of 111 participants losing weight, including 58% of youth and 73% of parents.

Parental participation in the program had a positive impact on youth attendance and weight loss, as well as a positive impact on parental weight loss. Results suggest that buy-in by parents serves an important motivator and reinforcer of youth participation and behavior change and are supported by findings of other researcher (10). In addition, HEROES investigators reported that providing weekly feedback on weight status through a computer model had a positive impact on participants. Investigators stated that participants who lost weight were excited and enjoyed receiving praise for their progress. Participants who maintained or gained weight tended to be disappointed, but were generally willing to discuss why they might be gaining weight and ways to make changes to their behavior.

The HEROES program materials and implementation processes can be made available to schools and community groups. In addition, we are interested in incorporating the HEROES lessons into our clinic-based weight management program.

HLP Clinical Outcomes and Patient/Provider Feedback

The ultimate goal of our weight management efforts is to reverse trends in pediatric obesity and related co-morbidities in SWP. In this effort, we set forth to determine the effectiveness of HLP on relevant health problems in overweight and obese children. Data collected in the Research Registry were analyzed to determine if a relationship exists between participation in the HLP weight management intervention program and clinical outcomes. The Research Registry is a database of medical information obtained from patients treated at the WMWC and community partners. Patients consent to participate in the Registry; as such, only data from consenting patients is presented herein.

Clinical Outcomes

Patient Demographics

All patients were referred to the weight management program by their primary care provider because patients were overweight or obese (defined as a Body Mass Index (BMI) $\geq 85^{th}$ percentile) and/or were diagnosed with obesity-related complications (i.e., hypertension, elevated blood lipids, sleep apnea). Of the 2,168 patients enrolled in the Research Registry, 71% (n=1,540) were Caucasian/Non-Hispanic, 23.7% (n=513) were African American, with the remaining 3.5% being Hispanic (0.8%), Asian (0.3%) or other/multiple race/ethnicities (2.4%). Patients' ages ranged from 2 to 20 years with an average age of 11.2 years.

Clinic Visits

Patient clinical visits ranged from 1 to 22 visits with an average of 2.9 visits. Of all referred patients who presented at the clinic, 55.4% returned for at least one follow-up visit. As shown in Table 2, most return patients presented for 2-3 follow-up visits with a significant percentage returning for 4 or more visits, indicating multiple exposures to the program. A relationship existed between rate of visits and time elapsed between visits (Table 3). The higher the rate of visits, the less time elapsed between visits, which may have been indicative of significant co-morbidities requiring more frequent follow-up. In addition, rate of visits corresponded to duration of program enrollment. Patients seen for 2-3 visits participated in the program for approximately 5 months, patients seen for 4-7 visits participated for an average of 13 months, and patients seen for 8 or more visits participated for as long as 22 months in the program.

Table 2. Rate of Clinic Visits by Patient Age Categories

Age by Visits	1 visit	2-3 visits	4-7 visits	8+ visits	Total
Age 02-05	111 (49.1)	60 (26.5)	35 (15.5)	20 (8.8)	**226 (11.1)**
Age 06-12	477 (45.2)	311 (29.5)	179 (17.0)	89 (8.4)	**1056 (52.0)**
Age 13-17	300 (42.3)	248 (35.0)	107 (15.1)	54 (7.6)	**709 (34.9)**
Age 18+	19 (46.3)	9 (22.0)	5 (12.2)	8 (19.5)	**41 (20.1)**
Total	**907 (44.6)**	**628 (30.9)**	**326 (16.0)**	**171 (8.4)**	**2032 (100.0)**

Table 3. Average Rate of and Duration Between of Clinic Visits

Average Rate and Duration	2 or 3 visits	4 to 7 visits	8 or more visits
Months between visits	4.1	3.3	2.3
Months from first to last visit	5.4	13.2	21.8

Baseline Data

At baseline, or initial visit, all patients were overweight or obese, with 53.1% (n=1,081) being extremely obese (BMI >99th percentile) (Table 4). Overweight and obesity can lead to a clustering of risk factors for CVD and T2DM known as metabolic syndrome (MetS) (11, 12). MetS, is characterized by abdominal obesity, abnormal blood lipids, elevated blood pressure, and abnormal blood glucose regulation. At baseline, 33% (n=1274) of patients had MetS. Percentage of patients who met at least one criterion for MetS were as follows: abdominal obesity (91.2%), elevated blood pressure (22.4%), elevated triglycerides (45.7%), low HDL-cholesterol (41.3%), and elevated blood glucose (7.1%). In addition, elevated LDL-cholesterol and total cholesterol were experienced by 37.9% and 44.4% of patients, respectively.

Table 4. Clinical Parameters at Baseline

Parameter	Patient Count 2168 / 2168	Prevalence 100%
Waist Circumference > 90th percentile *	1824 / 2000	91.2%
Blood pressure > 90th percentile *	450 / 2013	22.4%
Triglyceride > 110 mg/dL *	558 / 1220	45.7%
HDL-cholesterol <= 40 mg/dL *	500 / 1211	41.3%
Fasting Glucose >= 100 mg/dL *	70 / 987	7.1%
Metabolic Syndrome **	423 / 1274	33.2%
BMI > 99th percentile	1081 / 2035	53.1%

Percentages are based on non-missing data

* criteria for Stephen Cook's "Metabolic Syndrome" (Cook et al, *Arch Pediatr Adolesc Med.* 2003;157:821–7)

** defined as three of five criteria positive for subjects with at least three valid criteria measured.

Change in Clinical Outcomes

Change in clinical outcomes was assessed for patients for whom data was available for both baseline and most recent follow-up visit. Of patients at risk for MetS at baseline, 4% reduced their waist circumference (central adiposity) below the 90th percentile (p<.001); 8.5% lowered their blood pressure below the 90th percentile (p<.001), and 6% lowered their BMI below the 99th percentile (p<.001), thereby reducing their risk for T2DM and CVD (Figure 2).

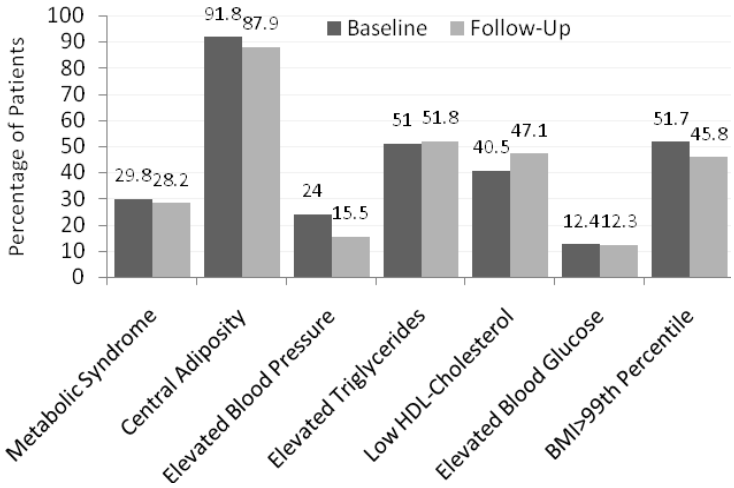


Figure 2. Change in Clinical Outcomes from Baseline to Follow-Up

A primary objective of the weight management program is maintenance or continued improvement of obesity-related clinical outcome measures. As shown in Table 5, improvements in blood pressure and BMI percentile significantly progressed across time. In other words, the longer the patient was enrolled in the program, the greater the improvement in the clinical outcome. Continued improvement, therefore, may be a result of adherence by patients to goals and behavior change strategies.

Table 5. Clinical Outcomes by Duration of Treatment

Clinical Outcome	**Treatment Group**			**Significance**
Mean difference base to follow-up	2-3 visits	4-7 visits	8+ visits	2p
Systolic Blood Pressure, mmHg	-0.34	-1.21	-2.14	0.1
n cases, std.dev.	*474, 10.5*	*303, 10.6*	*163, 11.2*	
Diastolic Blood Pressure, mmHg	-0.38	-1.50	-3.66	<0.001
n cases, std.dev.	*474, 9.1*	*303, 9.1*	*163, 10.0*	
Triglyceride, mg/dL	-4.985	-20.567	-5.636	0.8
n cases, std.dev.	*68, 80.2*	*67, 69.7*	*77, 63.7*	
HDL, mg/dL	-1.64	-0.94	+0.26	0.6
n cases, std.dev.	*67, 7.7*	*66, 8.0*	*76, 9.3*	
Fasting Glucose, mg/dL	-6.31	-3.48	-3.03	0.4
n cases, std.dev.	*29, 28.3*	*40, 13.3*	*30, 9.3*	
BMI percentile	-0.36	-0.90	-0.98	<0.001
n cases, std.dev.	*563, 1.2*	*318, 2.8*	*170, 3.2*	

Significances are from the: two-tailed Jonckheere-Terpstra test for ordered medians

Patient and Parent Satisfaction with HLP

The WMWC leaders with the aid of the CHP's Department of Marketing and Planning designed a survey to assess patient satisfaction to HLP, measuring access to care, clinical staff, satisfaction with the doctor's care, and overall visit.

The survey was given to the parent or guardian whose child had an appointment scheduled in the WMWC. A total of 61 surveys were returned and recorded. Responses to Likert-scaled items were scored on a 100 point scale, with 100 being the highest score possible.

As shown in Table 6, patients and parents rated HLP quite favorably. One hundred percent of respondents thought that everything went smoothly during their visits. Also of note, from a programmatic perspective, respondents thought the wellness advisor gave clear instructions (mean score 94.3/100), found learning materials to be helpful (92.6/100), and thought reasonable goals were set for their children (94.0/100).

Lowest scores were given to ease of finding the WMWC and ease of reaching office staff during office hours. Both of these factors have been noted and we are working to improve the accessibility and availability of office staff to respond to telephone calls as well as to clarify directions to the clinic and increase signage.

Table 6. Patient and Parent Satisfaction Ratings

Survey Items	Mean Score (100 points possible)
Access to Care	
Ease of scheduling appointment	93.6
Length of time before appointment was available	88.8
Ease of reaching office staff during office hours	84.9
Ease of finding the WMWC	83.8
Your Visit	
Everything went smoothly during your visit	100.0
Overall quality of care	93.2
Registration person who greeted you at the front desk	86.6
Courtesy and helpfulness shown to you by office staff	92.2
Wellness advisor giving you clear instructions	94.3
Helpfulness of learning materials provided	92.6
Reasonable goals were set for child	94.0
Clinical staff	
Quality of care provided by nursing staff	93.4
Quality of care provided by nurse practitioner or physician's assistant	94.5
Quality of care provided by resident or medical provider	93.8
Doctor Care	
Overall quality of doctor care	92.0
Doctor's instructions or explanation of child's medical condition or treatment	89.6
Your impression of the doctor's medical skills	93.5
Doctor taking time to talk to child about condition	89.3
Amount of time spent with you and your child	87.4
Doctor's understanding and caring	90.6
Doctor saw your child in reasonable time after you spoke with nurse	90.4
Doctor being thorough with physical exam	89.1
Doctor listening carefully to you and your child	91.3

Open-ended Items
Did something or someone stand out as exceptional during your visit? Please explain.
• Wellness advisors were positive, inspirational, helpful, or listened well. (n=6) • Physicians/nurses were great, pleasant, and/or nice. (n=5) • The doctor listened very well and answered questions. • Both the physician's assistant and nurse were excellent with my son, particularly at the teenage level. • Excellent service, caring attitudes (n=2) • Appointment moved along well considering all the people we needed to see. • Everyone spent time explaining things to us. Usually you are in & out of appt. We appreciate the time spent. • Very understanding and never critical • Security guard came out to the street to help direct me to where I needed to be. • I liked Jill, guard at parking garage helpful
Additional Comments
• Great experience (n=2) • The service is great, fast, and wonderful. • Excessive questionnaires • The initial paperwork is too much- some of we were not able to answer • The whole staff was wonderful • Parking garage is difficult • Very helpful program • Dr. asked questions—listened carefully; didn't say too much. • We look forward to the next visit.

Patient Success Stories

We have included two accounts from patients who successfully lost weight to demonstrate the impact our weight management program. As evidenced by the following accounts, patients who are motivated to change their behavior, adhere to the advice given by our clinical staff, take an active role in their behavior change, and are supported by their parents and families are successful at improving their physical health and emotional well-being.

Summer Heasley

Summer Heasley is a healthy, active third-grader who loves to play at the park, walk with her mother, Susan Heasley, and dance around her house in Leechburg.

However, Summer wasn't always a bundle of energy. Less than a year ago, she lived the life of a sedentary pre-teen who, like many school-aged children, was overweight. At eight years old, Summer weighed 105 lbs. and had a body fat content of 40.6 percent when she was referred to CHP's WMWC by her pediatrician. Ten months later, Summer is proud to say that her fat content has dropped to 19.9 percent, and she has lost 16.3 cm in her waist.

"It was the best thing her pediatrician could have done," explains Susan Heasley. "Referring Summer to CHP's WMWC was the first step in getting her to where she is today."

Summer and her mother traveled to Oakland for her first consultation in early December 2007. The pair met with Lindsey Detwiler, RD, LDN, clinical dietitian and wellness advisor, and John Weidinger, PA-C, physician assistant. She underwent a medical exam, nutrition and physical activity assessment, and a behavioral assessment. Ms. Detwiler thinks this multidisciplinary approach is what makes the program so successful.

Summer's first task was to change her eating habits, which meant including five fruits and vegetables a day and eliminating the fats and sweets. She also was to begin exercising three times a week. These were two of the Healthy Lifestyle Goals she had set for herself at the beginning of the program.

"John and I both agree that much of Summer's success is attributed to the entire family's commitment to adopt a healthier lifestyle," says Ms. Detwiler. "When she came back for her follow-up in January, she and her family already were successful in having more family meals seated at the table, choosing healthier foods, decreasing portion sizes and increasing physical activity."

Summer returns every two months to the WMWC for an appointment to monitor her progress. Detwiler and Weidinger measure her height and weight, check up on her physical activity and evaluate her overall health. They also measure her body fat with an egg-shaped machine Summer refers to as a "bod pod."

"I love to run and swim now, and I exercise five times a week," Summer says. "And we make this great low-fat pizza at home, so I still get to eat things I like. I feel good about myself and I'm happier."

Although many would probably consider Summer's statistics remarkable given her ten-month involvement in the program, Ms. Heasley continues to be thankful for all of the positive changes she's seen in her daughter.

"The changes I see in Summer are remarkable," expresses Ms. Heasley. "She has so much more self-confidence — she lets her sense of humor shine now. Summer has gotten sick fewer times, and she can't read a book without tapping her foot from excess energy. It's a mother's dream, and I thank CHP's WMWC for helping Summer to become happier and healthier for life."

Marco Petersen

A lacrosse player dashes farther down the field, breaks free from his defender and delivers the ball into the net, cheered on by fellow high school teammates and parents on the sidelines. The player is 11th-grader Marco Petersen. Just like other athletes, he prides himself on discipline and hard work—two qualities that have made him successful in more than sports alone.

Since January 2008, Marco has been a patient at the WMWC of CHP. Once an overweight young man with poor eating habits, he has transformed into an active athlete who maintains a healthy lifestyle.

"The key for Marco has been motivation—he made the commitment himself to change and make the effort to eat healthfully and be active," says Anne Marie Kuchera, MS, MA, RD, a behavioral therapist and nutritionist for the center. "Our specialists worked with him to promote gradual weight loss over time, but his success was primarily driven by his own determination. He also has an incredibly supportive family."

When Marco first came to the WMWC, he had a Body Mass Index (BMI) of 31.21 and a waist circumference of 101.5 cm, indicating obesity. Center specialists assessed his measurements, lifestyle habits, activity level, diet and history of losing and gaining weight. Following the appointment, Petersen began to make several changes in his life.

"It definitely was intense at first," says Marco. "I joined the lacrosse team, and I had to make a lot of changes to my eating habits. No matter when it was, I always wanted to come back to the (Weight Management and Wellness) Center having made progress."

Ms. Kuchera says that the statistics reveal his incredible progress. Between the end of January 2008 and Oct. 15, 2008, Petersen lost 17.5 cm off his waist, his BMI dropped nearly six points and his body fat percentage has decreased significantly.

More than a year later, Marco returns to CHP's WMWC every two or three months. He has made the necessary changes to his diet and lifestyle, so now he works to maintain his weight.

"Originally Marco worked very hard to change his lifestyle habits, and now the goal is maintenance," says Ms. Kuchera. "We continue to discuss how to make healthy food choices that will allow him to manage his weight and perform well in lacrosse, how to stay active when he does not have the structure of the sport, and how to maintain a balance between discipline and living the life of a normal teenager."

Susan Petersen, Marco's mother, has continued to be impressed by her son's self-motivation and independence. She explains that, although their family made some changes together, Marco held himself accountable for the choices he was making.

"I can see how rewarding it's been for him," says Ms. Petersen. "His self-confidence is soaring—not only because he looks and feels great, but because he knows he can thank himself for a lot of his success."

Provider Feedback

Clinical Director Dr. Rao and Wellness Advisors Lindsey Detwiler, RD, LD, and Mallory Lang, RD, LD, offered a provider's perspective on the HLP weight management program.

- Patient Interactions: In general, interactions between patients and providers have been overwhelmingly positive. Parents are grateful to find a clinical service to meet their children's weight management needs. Furthermore, we have received much praise from patients and parents about the sensitive approach we take to the problem of obesity. A majority of patients and parents leave satisfied with their clinical experiences. Patients are aware that they will spend a significant portion of their day at the clinic during their initial visit. Even so, they may become frustrated if the wait time between seeing clinicians is prolonged. The quality of patients' nutrition/fitness counseling can be affected due to such time constraints. It is our goal to decrease wait time in order to improve patient and parent experiences in the weight management program.
- HLP Principles: The core principles of our clinical program include focus upon key behaviors responsible for obesity, and strategies that include motivational interviewing and behavioral contracting. Patients seem to really appreciate our "non-diet" approach. Simply giving a patient a calorie goal is not nearly as effective as helping the patient/family to recognize their habits and make lifestyle changes. However, there is always pressure to incorporate more intense, group approaches, which can, at best, accommodate a small number of children. A challenge for the future is to establish a consistent theoretical foundation for the services we provide. This will require discussion and agreement among the leaders of the weight management program.
- Multidisciplinary Approach: Just as there are many factors that can contribute to obesity, many specialties should be used to handle the issue. For example, a patient/family may have some nutrition knowledge, but behaviors surrounding food are leading to their obesity. This is why a multidisciplinary approach is needed to tackle obesity.
- Community Impact: The impact upon the community has been substantial. Our weight management services have been expanded to community-based pediatric practices in several underserved communities throughout SWP. The level of service offered depends on the needs of the community, availability of clinical space, and, in some cases, availability of personnel. Overall we have managed to create a presence in three regions of SWP, the Southwestern region close to the state of West Virginia, the rural region east of Pittsburgh, and the Johnstown/Cambria County region.

  A large number of children have been cared for directly in the WMWC and community outreach practices. More importantly, a large number of community-based providers have been influenced through seminars, workshops, lectures, and individual contact with the WMWC's providers to improve their care of overweight and obese children. The end result is a large group of providers in our region who take the problem of childhood obesity seriously and have the skills to manage the problem rationally.

Summary

A significant percentage of patients successfully decreased their body weight, central adiposity, and blood pressure as a result of participating in our weight management program. Adult obesity and hypertension are leading causes of CVD morbidity and mortality. Previous research indicates that elevated blood pressure and BMI in childhood have an additive effect in predicting the highest levels of young adult CVD risk (13). Furthermore, central adiposity is an independent predictor of insulin resistance and is a key risk factor for T2DM and CVD (14, 15). Thus, successful reductions of these factors, as demonstrated by our program, have important long term health implications. Furthermore, our results emphasize the benefit of early detection followed by family-based lifestyle intervention as an effective method of pediatric obesity treatment and chronic disease prevention.

HB4Life Program

HB4Life is a secure Web portal focused on pediatric weight management education, meal planning, physical activity and goal setting and serves as the Web-based component of HLP. The weight management portal is an extension of interactive web tools (Healthy Plate and Big 5 Tracker) developed for the CHP's WMWC as part of their lifestyle behavior modification program. Web-based behaviorally-focused programs provide a fun, familiar, and convenient format to engage children in weight management education and empower them to make healthy diet- and activity-related choices.

Methods

Design

HB4Life was designed through a collaborative effort of health professionals from the CHP WMWC, Web communication specialists from the CHP Public and Government Affairs office, and Web designers from Etcetera Edutainment, affiliates of Carnegie Mellon University. WMWC health professionals conceptualized the Web site based on pediatric weight management practices and provided content for the Web portal. CHP Web communication specialists translated content into a usable Web format, created a site map, and provided oversight to Web site designers.

Web Site Components

Two interactive educational tools – Healthy Plate and the Big 5 Tracker – are the focus of HB4Life. These interactive tools were developed to educate patients about dietary and weight-related behaviors and to encourage program adherence through active engagement in behavior change. Healthy Plate is a tool that allows children to track their food choices throughout the day. Children add food to a virtual "plate" by clicking-and-dragging food items selected from a database. The application calculates calories and nutrients for food choices and meals and presents data in a tabular format. The Big 5 Tracker allows children to record their behaviors with respect to five principal habits related to obesity – sweet beverage consumption, fast food consumption, frequency of family meals, habitual physical activity, and sedentary television and media time. Responses to the Big 5 Tracker habits and Healthy Plate calories and nutrient intake are scored daily on a scale of 0 to 100; scores of 80 or above are considered excellent. Scores for each behavior are also graphed to provide visual representations of behaviors for a week's time. The secure Web-based tools function on the premise that children will regularly record diet and lifestyle behaviors. Data is saved to enable children, families and clinicians (the latter through an administrative function) to review past entries and assess progress across time.

HB4Life is also a rich informational resource, including descriptions of the HB4Life program and healthy lifestyle behaviors as well as tailored educational materials specifically designed to address issues salient to children, teenagers, and parents. In addition, the Web site also showcases patients who have successfully reduced and managed their weight and related co-morbidities by following HB4Life guidelines. Finally, the Web site includes contact information

Training

WMWC wellness advisors train patients, parents, and providers on how to enroll in HB4Life and use the interactive tools (e.g., Healthy Plate and Big 5 Tracker). Patients and parents receive a demo of the interactive tools during their clinical assessments and goals set during the visits are incorporated into the online behavior contract. Wellness advisors also provide training to other health professionals interested in using the interactive tools for educational purposes in school or community program settings.

Promotional and Communication Tools and Incentives

The CHP marketing department developed promotional and communication tools to introduce both patients and providers to the Web portal and encourage their participation in the program. Promotional efforts directed towards providers are intended to foster support of the Web portal and communication to patients. Community-based health providers and staff are provided with notepads, pens, mugs, and post-it-notes that contain the HB4Life.com logo in

order to promote the Web portal to patients. Promotional efforts directed towards patients are designed to peak interest in participating in the Web portal activities and serve as incentives for continued participation; the more patients willing to participate and use the Web portal, the more beneficial it becomes in terms of reach and collection of data on youth eating and activity behaviors. The CHP marketing department created shoulder bags for youth who register on the Web portal. Each bag contains a water bottle, a pedometer, and an educational card about the Healthy Plate and Big 5 Tracker.

Findings

Implementation

HB4Life was integrated into the weight management program on 10 February 2009. Wellness advisors introduce patient and parents to the Web portal during routine clinic visits. Patients and parents are provided with an informational brochure explaining how to enroll into the HB4Life program and use the interactive educational tools. As previously mentioned, wellness advisors also demonstrate how to enter information into Healthy Plate and the Big 5 Tracker. In addition, patients are provided with the promotional/incentive package consisting of a shoulder bag, water bottle, pedometer, and educational card. Wellness advisors have reported that youth are particularly excited about receiving the pedometers.

Once patients and parents enroll into the HB4Life program, wellness advisors are able to monitor information entered into Healthy Plate and the Big 5 Tracker. The information recorded can then be discussed during follow-up clinic visits or patients/parents can contact wellness advisors in between visits to ask questions.

Outcomes

To date, 174 patients have registered and enrolled in the HB4Life program. A majority of the patients enrolled are female (68%). A total of 16 providers in SWP have referred patients to the HB4Life program (Table 7).

Table 7. HB4Life Patients and Referring Providers

Results	N (%)
Patients enrolled in HB4Life	174
Female	118 (68%)
Male	56 (32%)
Providers referring patients to HB4Life	16

Patients and parents have provided positive feedback to the HB4Life program. They have reported that they like the program and have found it to be very helpful in assisting with portion control, staying consistent with goals set during clinical assessments, and increasing their awareness of weight-related behaviors.

The HB4Life program has also received favorable reviews from CHP health professionals, WMWC staff, and web developers. All invested parties are excited about the product and look forward to following its success. Numerous health professionals have requested demonstrations of HB4Life so that they can use the Web site as an educational tool in clinic, school, and community-based settings. For example, CHP's Community Pediatrics (CCP) network and the UPMC Health Plan (insurance group) have communicated extreme interest in utilizing HB4Life within their primary care practices and group programs. In addition, Dr. Goutham Rao, WMWC clinical director, described the HB4Life program during an interactive webinar on obesity and metabolic syndrome in adolescents sponsored by the National Initiative for Children's Healthcare Quality. Dr. Rao received hundreds of requests for the HB4Life Web address from webinar participants.

Summary

HB4Life serves as an educational resource to teach patients how to adopt lifelong healthy behaviors and as a site to track behaviors (via Healthy Plate and Big 5 Tracker) across time. Provision of data on the web-based educational tools is used to facilitate and guide wellness advice in follow-up clinic visits. We are currently conducting a randomized control trial to compare the usefulness of the web-based tools against the standard clinical educational protocol in improving weight status and related conditions among weight management program participants. Findings from this study will help inform the utility of the web-based educational tools.

Furthermore, we plan to incorporate HB4Life into primary care of overweight and obese patients. A benefit of the web portal is that pediatricians who may not have the means to implement our full behavior-based program can adopt the web portal as a means of extending the weight management advice that they give patients. We also look forward to promoting HB4Life to schools and community-based programs as a way to teach children about healthy eating habits and lifestyle behaviors.

Military Populations

Efforts to deploy pediatric diabetes prevention and weight management programs in a military setting were accomplished as part of this award by implementing two forms of HLP at WHMC:

1. HLP Clinic-Based Lifestyle Intervention Program
2. HB4Life Program, an integrated weight management Web portal

HLP Clinic-Based Lifestyle Intervention Program

The SAMPC Pediatric Wellness Center diabetes prevention and weight management program is built on an evidenced-based model for primary prevention and management of pediatric obesity referred to HLP. In partnership with the AF, the diabetes and obesity prevention and treatment model developed at CHP was used to establish a clinical program at WHMC following the same HLP principles and protocols in place at CHP.

Methods

To explore implementation of HLP at WHMC, a project team was formed that included CHP and WHMC project investigators and representatives of the Air Force and Surgeon General's Office. The project team held meetings to discuss the weight management program and to determine which components could be implemented at WHMC and what requirements needed to be addressed in order to realize implementation.

It was determined (13 November 2007) that the core components of the program - medical, wellness, and psychosocial assessments – would be implemented at WHMC by a wellness team through one-on-one visits with pediatric patients and their guardians. This goal would be met by following HLP clinical protocols and procedures established at CHP, hiring appropriate clinical staff, and securing necessary equipment and facilities.

An action plan was devised to facilitate implementation of the weight management program at WHMC. The action plan was followed to systematically address initial implementation requirements and to continue program development and expansion. Although the decision was made to implement the existing CHP WMWC clinical protocols and procedures, the project team had to address operational factors and requirements that were unique to the military, including the military's electronic medical record system and regulatory procedures.

Findings

HLP Clinical Protocols and Procedures

The SAMPC Pediatric Wellness Center patient population includes children and youth of either sex and any race or ethnic background, aged 2 – 22 years, with a body mass index (BMI) $\geq$ 85th percentile for age and sex.

Primary care providers at WHMC and BAMC refer patients to the SAMPC Pediatric Wellness Center if the child has a BMI $\geq$ 85th percentile and/or weight-related health conditions or disorders (i.e., hypertension, dyslipidemia, polycystic ovary syndrome). Referrals from WHMC and BAMC physicians are made on an ongoing basis.

The following multidisciplinary outpatient model developed at CHP for the care of obese children that includes assessment and treatment of obesity and obesity-related illnesses was adopted for use at WHMC (Table 1).

Table 1. HLP Clinical Protocol

Initial Visits (2-2.5 hours)

1. **Medical Assessment**

The overall purpose of the medical assessment is to identify any medical or psychological co-morbidities of obesity, identify key habits related to obesity, and make an overall assessment of each child's (and family's) motivation to lose weight and resources available for the weight management effort. Specific elements of the medical assessment include the following:

- Past medical and surgical history
- Family history of obesity-related illnesses
- Principal obesity-related habits (sweet beverage consumption, fast food, media time, family dining habits, and habitual physical activity)
- Developmental history
- Review of systems
- Physical exam with focus on identifying obesity-related signs (e.g., acanthosis nigricans)
- Routine laboratory testing:
  - Fasting glucose or oral glucose tolerance test (Screening for diabetes)
  - Fasting lipid profile (Sever hyperlipidemia in older children is treated with medication. For others, the presence of hyperlipidemia is presented to families as another motivation to lose weight.)
  - BUN/Creatinine (Routine test of renal function)
  - Dipstick urinalysis (Routine screening for proteinuria and urinary glucose)
  - AST, ALT (Screening for non-alcoholic fatty liver disease)

The medical assessment follows closely the recommendations of the American Medical Association's Expert Committee on Identification, Assessment, and Treatment of Child and Adolescent Overweight and Obesity, of which Dr. Goutham Rao, Clinical Director of the CHP WMWC, is a member. The screening procedures are based on the American Diabetes Association Consensus (6) of which Dr. Silva Arslanian, Director of the CHP WMWC, was one of six participating pediatric endocrinologists. The treatment of hypertension and dyslipidemia is based on the American Diabetes Association Consensus (7) of which Dr. Arslanian was one of the participating pediatric endocrinologists and cardiologists. There is little point in "customizing" this routine laboratory panel for individual patients. Almost all patients will have BMI > 95th percentile with one or more signs of insulin resistance and a family history of obesity-related problems. All the above tests, therefore, are justifiable since the vast majority of patients have multiple risks for obesity-related illnesses.

2. **Wellness Assessment**

The principal goal of the wellness assessment is to identify lifestyle habits contributing to obesity and to negotiate a written agreement with a family to change behaviors, incrementally over time. Specific components include:

- Identification of specific unhealthy dietary habits (e.g., frequent consumption of fast foods and/or soda drinks, breakfast skipping, eating large portions, etc.). A food frequency questionnaire is used for this purpose.
- Identification of current level and type of physical activity and sedentary behavior.
- Identification of motivation of child and family to make behavior changes in areas

where they are most needed.

- Identification of perceived and tangible barriers to change.
- Negotiation of a Healthy Lifestyles Goals Agreement based on identified behaviors, child's preference for which behaviors to change, and parents' preference for which behaviors to change.

The underlying principles of the wellness recommendation are the following:

- The overall goal should always be promotion of healthy lifestyle habits. If habits become healthy, weight will take care of itself.
- Diets and other "quick fixes" are largely unsuccessful in children.
- Incremental behavior change in which children and families play a role in deciding which behaviors to change and how quickly is more likely to be successful than drastic behavior change.
- Behavioral or contingency contracting is an effective tool for changing patient behavior.

3. **Psychological Assessment**

The overall goal of the psychological assessment is to identify behavioral or psychological illness that may interfere with the weight management effort and to identify behavioral or psychological problems that are contributing to weight gain and address them if necessary.

Follow-Up Visits (45 minutes to 1 hour)

The routine periodicity of follow-up is every 2 months. Patients with significant co-morbidities may be seen more often. Highly successful patients may be seen less often. Follow-up by telephone and email is always available to all patients with wellness advisors, psychologists, and medical staff. The purpose of routine follow-up visits is the following:

- Re-assessment of any medical co-morbidities and appropriate treatment and referral as is necessary.
- Assessment of progress in meeting behavioral goals. Identification of reasons for failure to achieve goals, and re-negotiation of Healthy Lifestyle Goals Agreement as needed.

Lifestyle Intervention Manual

Developed in collaboration with CHP, this manual includes a series of 13 lessons to guide patients through the HLP weight management program. At the initial visit, wellness advisors help patients and parents to identify salient behaviors and factors that contribute to their weight status. Wellness advisors then formulate a plan and utilize lessons and associated materials included in the manual to enable patients and parents to systematically and incrementally address obesity-related behaviors and factors. The 13 Lifestyle Lessons and related topics are listed in Table 2.

Table 2. HLP Lifestyle Intervention Manual

Lesson	Topics
1. Eating for Weight Management and Wellness	• Reading nutrition labels • Making healthy beverage choices • Healthy plate • Portion sizes
2. Moving for Weight Management and Wellness	• Getting started with physical activity • Reducing sedentary activity • Being active all-year round
3. Eating Well While Dining Out	• Making healthy choices at school and in restaurants • Planning for special occasions • Planning ahead for healthy snacks
4. Eating Well at Parties, Holidays, and Special Occasions	• Planning for holidays, parties, and special occasions. • Planning a healthy occasion • Problem solving various challenges
5. Mindful Eating	• What is mindful eating? • Recognizing hunger vs. satiety
6. Shopping and Meal Preparation for Weight Management and Wellness	• Stocking your kitchen • Healthful cooking methods • Quick and cost-conscious recipes
7. Facing Barriers and Overcoming Challenges to Weight Management	• Becoming aware of barriers and challenges • Overcoming barriers and challenges • Five steps to problem solving
8. Dealing with Teasing and Bullying	• Types of teasing and bullying • Reasons for teasing/bullying • Ways to “tackle” teasing • Strategies for parents
9. Eating and Your Emotions	• What is emotional eating? • Relationships among thought, emotions, and eating • Overcoming emotional eating
10. Building a Healthy Body Image	• What is body image? • Myths that impact body image • Building a better body image
11. Increase Your Self Esteem	• What is self esteem? • The benefits of building self esteem • Seven steps to increase your self esteem
12. Smart Snacking	• What smart snacking is and isn’t • Smart snacks for kids • Creating a smart kitchen
13. Making Lifestyle Changes…for Life	• Staying Motivated • Planning to stay active and eat well • Maintaining a positive attitude • Future goal setting and planning

HB4Life

Patients and families treated at the SAMPC Pediatric Wellness Center are encouraged to use the HB4Life Web portal as an educational resource to learn how to adopt lifelong healthy behaviors and as a site to track behaviors (via Healthy Plate and Big 5 Tracker) across time. Provision of data on the web-based educational tools can then be used to facilitate and guide wellness advice in follow-up clinic visits. A more comprehensive description of HB4Life is provided in a subsequent section of this report.

Educational Resources

A variety of educational handouts are available to patients and parents to supplement counseling and subjects discussed during clinic wellness visits. Table 3 lists available handouts by topical area.

Table 3. Educational Resources

Topic	Handouts
1. Nutrition	• Using the Healthy Plate to guide meals and snacks • Foods to choose. Foods to limit. • Basic calorie counting • Sample meal plans (1000, 1200, 1400 1600)
2. Activity	• Get moving all year round • My child refuses to exercise. What should I do? • Watch less. Do more. A guide to TV viewing • Exercise videos • Using a pedometer to help you be more active
3. Tracking	• Lifestyle logs • My weight • Feeding guide log for children 2-3 • Feeding guide log for children 4-6
4. Dining Out	• Fast food guide • Going out to eat
5. Mindful Eating	• Managing cravings • Un-sneak your eating • Hunger/fullness scale • Simple hunger scale • Mastering the mindful meal
6. Emotional Eating	• Relaxation techniques and coping skills • Thoughts, emotions, and eating • Food/mood chart
7. Body Image	• Parents, how you can promote your child's body image • Ten steps to a positive body image • Helpsheet for change
8. Shopping and Meal Preparation	• Healthy and thrifty meals recipe book • Healthy shopping list • Choose this, not that • Kitchen activities for preschoolers
9. Overcoming Challenges	• ACT and THINK • Problem solving
10. Special Occasions	• Party problem solving
11. Parent	• Creating positive family meal times • Help! My child won't eat fruits or vegetables • Helping your child develop healthy habits • Positive parenting skills

Local Resources

SAMPC Pediatric Wellness Center wellness advisors compiled a set of local resources available to patients and parents to aid them in their goal of weight maintenance. The resource guide includes information on several programs, including Lackland Air Force Base fitness centers and personal trainers and Fit Factor. Fit Factor (http://www.afgetfit.com/Home.aspx) is an Air Force-wide internet-based program designed to encourage youth and teens ages 6 to 18 years to improve their health and activity level and increase their awareness of and participation in Air Force programs and services. The program has an interactive component through which youth record their daily activities. Youth receive points for each activity; points can then be turned in for prizes. While Fit Factor is an Air Force-wide program, it includes base-level management, such that youth are able to identify and participate in base programs and retrieve prizes from a local source. Additional local resources will be added to the list as they are identified.

Utilization Rates

The SAMPC Pediatric Wellness Center wellness team started seeing patients on November 12, 2008. To date, 207 new patients and 206 follow-up visits have occurred, for a total of 413 patient encounters (Table 4). The Center's patient slots are completely full through mid-February 2010.

As shown in Table 4, approximately 42% of referred patients presented to the SAMPC Pediatric Wellness Center for an initial appointment. Center staff makes 3 attempts (2 phone calls and 1 mailed letter) to schedule appointments with referred patients. We are uncertain as to why patients do not schedule appointments after being referred by their primary care provider, but we did note an increase in new patients after disseminating pocket cards and informational brochures to providers and clinics. No-show rates are similar at the CHP weight management program.

Table 4. HLP Utilization Rates

Category	Patients (n)
Referrals	495
Total patient encounters	413
New patients	207
Follow-up visits	206
Cancellations	143
No-shows	107

Patient/Provider Feedback

Wellness advisors reported that most families are receptive to educational resources provided as part of the HLP program and seem to understand the program's core principles. Patients who comply consistently see much progress in their weight-related behaviors and compliant patients have lost weight and many are now within a healthy weight range. However, many patients are unmotivated or lose motivation in between clinic visits. In addition, wellness advisors have found that many parents do not enforce the goals when the patient complains about not receiving the types of foods they desire. In addition, wellness advisors have found the lifestyle intervention manual's lessons and resources to be extremely helpful in providing structure to the program and giving patients an at-home reference.

Summary

A project team of CHP and WHMC health and military officials collaborated to implement core components of HLP at WHMC. HLP principles and protocols developed at the CHP were adopted at WHMC. An action plan guided implementation of the program, hiring and training of staff, and securing appropriate materials and equipment. Core components of HLP have been successfully implemented at WHMC. In addition, HLP has been expanded upon to include a Lifestyle Intervention Manual, which provides a systematic approach to implementing the weight management program.

Space and staffing issues have been ongoing challenges. Lack of space is also an issue faced by other outpatient clinics at WHMC. Currently, our clinic is sharing space with other WHMC subspecialty clinics. Presently, we are at full capacity for scheduling patient visits; our template cannot be expanded until additional space is identified. Temporary solutions to space issues are being actively pursued; to date, long-term solutions have not been identified. In terms of staffing, we experienced significant delays in hiring clinical staff, which did impact the number of patients we were able to see in the beginning of the program as well as limited the scope of the HLP program. We have also experienced staff turnover for some positions, which impacts that program. However, our success at recruiting eligible candidates for positions has improved in recent months, likely an outcome of improvements in our recruitment strategies.

The HLP clinic-based intervention continually evolves as our understanding of childhood obesity and related factors increases and as scientific research in the area grows. As such, we will refine and enhance our program and health care delivery methods, incorporating lessons learned from our experiences and advancements made in the field of childhood obesity. Additionally, as part of future funding, we will conduct an evaluation of the impact of the HLP clinical intervention program on pediatric obesity in our military patient population and assess progress in weight status and clinical parameters and relationships among weight, ethnicity, parental deployment, and geographical location.

HB4Life Program

The HB4Life program, described earlier in this section for the civilian population, was also implemented at the SAMPC Pediatric Wellness Center at WHMC. Descriptions of design, Web site components, training, promotional and communication tools and incentives, and implementation procedures also apply to the HB4Life program at WHMC. Information specific to WHMC, including informational technology (IT) requirements/testing, training, and outcomes are described herein.

Methods

IT Requirements and Testing

The Web-based tools were first tested by Etcetera Edutainment and CHP with youth in the Pittsburgh area and determined to meet programming and users needs. However, to implement the tools at WHMC, approval is required by the AF and Web-based components must be tested by the AF Medical Information Systems Test Bed (i.e., AF test bed team). The CHP project team provided the test engineers of the AF test bed team with documentation that addressed IT requirements, tool design and structure, site testing, and user testing from their Web developer. The documentation was provided to assist the AF test bed team with their further evaluation of the IT requirements of the Web-based tools and Web portal. The test bed team evaluated the documents, assessed the IT requirements and security status of the Web-based tools and devised a protocol for conducting usability testing of the Web-based tools with patients from the SAMPC Pediatric Wellness Center.

The AF test bed team submitted an Operational Utility Evaluation report on 22 September 2009 detailing their evaluation procedures and outcomes. As described in the report, the test bed team concluded that "Users had mixed opinions in assessing system usefulness, ease of use, and productivity. In conjunction with increased user training, human-computer interaction issues can be addressed in order to improve future application updates. The value of tracking dietary and physical activity data in a consistent manner offers great value, but more research and analysis is needed to determine the best presentation of these tracking tools. Until issues are resolved, deployment of HB4Life will result in mixed success outcomes."

Training

SAMPC Pediatric Wellness Center wellness advisors and staff attended a pre-training session in February 2009. Project leads and wellness providers discussed, in detail, all aspects of the web portal and how to train patients on using the web portal. Center staff members hired after this date were also trained upon joining the clinic team.

Findings

HB4Life.com was integrated into the weight management program on 16 March 2009. To date, 110 patients have been introduced to HB4Life and 17.3% (n=19) have registered and enrolled in the HB4Life program. Approximately an equal number of males (n=10) and females (n=9) have enrolled in the program. The percentage of patients enrolled in HB4Life is similar to the enrollment rate at the CHP weight management program.

Patients and parents have provided positive feedback to the HB4Life program. According to Rayna Wooten, SAMPC Pediatric Wellness Center wellness advisor, families are excited about the Web site, both as a way to monitor behavior and to access listed resources and usually feel it would be a good program for them. Most patients that have logged onto the Web site have stated it is easy to use. Interestingly, parents generally express more willingness to use it than patients. Some teenagers have expressed that they don't feel the site is age appropriate (most teenagers feel that it is geared towards children). Other patients have stated that they have forgotten to use it or that they didn't have enough time. A few patients have reported that they prefer to keep a handwritten journal instead of using the Website to track behaviors.

Wellness advisors stated that they utilize the HB4Life program as educational tool to introduce topics and resources to patients and parents. They reported that the program enhances their counseling session with patients. In addition, they have found the

meal and activity tracking tools available through the administrative function of the Web site to be useful for monitoring patients' dietary habits and behaviors and serve as a reference to patients' verbal reports provided during clinic visits.

Summary

The HB4Life web portal will be routinely updated in order to communicate the latest research on pediatric weight management and healthy behaviors. We will also use patient and family feedback to ensure their informational needs and interests are met and outcomes of the AF test bed team's Operational Utility Evaluation report to address usability and functionality issues. In addition, we plan to expand the patient success stories section. Furthermore, at CHP, we are conducting a randomized control trial to compare the usefulness of the web-based tools against the standard clinical educational protocol in improving weight status and related conditions among weight management program participants. Findings from this study will help inform the utility of the web-based educational tools. Finally, continued use of HB4Life at WHMC is ultimately contingent on formal approval by the AF, which relies on their review of the Operational Utility Evaluation made by the AF test bed team.

Geographical Expansion of the Research Registry

The Research Registry is a research database of medical information obtained from patients treated in our weight management programs at CHP and WHMC. The primary purpose of the Research Registry is to track clinical course and outcomes of pediatric patients. As such, the Research Registry provides data on the effectiveness of obesity intervention and treatment strategies employed by the program. In addition, the Registry is used to perform retrospective research studies on childhood obesity and related conditions and identify patients who may be eligible for participation in future research studies.

Civilian Populations

In the civilian population, our objective was to geographically expand the reach of the CHP WMWC Research Registry through recruitment of potential participants from communities outside the greater Pittsburgh area, the original catchment area established in prior works. Following is a description of the methods for meeting this objective and the outcomes of our efforts.

Methods

All patients presenting to the WMWC clinics were offered participation in the Research Registry. Youth of either sex and any race or ethnic background, aged 0-18 years, with a BMI $\geq 85^{th}$ percentile for age and sex were asked to participate. Participants in the Registry are geographically identified by a unique 5-digit zip code. The study period for geographical expansion of the Registry was defined as 100% increase in Registry participation from the date of June 30, 2007, at which time 812 patients had consented to participate in the Registry. We tracked the number of consenting patients after this date until the Registry doubled in size. When the Registry had doubled in size, which occurred on August 11, 2008, we assessed the number of new zip codes that were added to the Registry. We looked at the total number of new unique 5-digit zip codes as well as the geographical location of the zip codes within SWP. This information was used to determine if we had indeed recruited participants from communities outside the original catchment area. The city of Pittsburgh was the focus of the original catchment area.

Results

As previously stated, the study period for geographical expansion was defined as 100% increase in Registry participation from the date of June 30, 2007. As of this date, 812 patients had consented to the Registry. The Registry doubled in size on August 11, 2008 to a total of 1, 625 participants. Therefore, we compared the number of unique 5-digit zip codes between the pre-study time period (August 29, 2006 to June 30, 2007) and the study time period (July 1, 2007 to August 11, 2008) to assess geographical expansion of the Registry.

As shown in the table, by August 11, 2008, the Registry had doubled in size to 1,625 participants. During this time period, the number of unique 5-digit zip codes increased from 224 to 312 zip codes. This means that an additional 88 unique 5-digit zip codes were added to the Registry during the study period. The additional 88 zip codes represented 114 Registry participants. Of those 114 participants, 3 were from city of Pittsburgh, 5 from other areas of Allegheny County, 40 from the 5 counties surrounding Allegheny County (Counties of Armstrong, Beaver, Butler, Washington, and Westmoreland), and 66 from other counties in SWP and nearby states (Ohio, West Virginia, and Maryland).

Table 1. Geographical Expansion of the Research Registry

	Baseline June 30, 20007	Follow-up August 11, 2008	Change
Number of participants	812	1,625	813
Number of unique 5-digit zip codes	224	312	88

Summary

The Research Registry serves an important role in our efforts to address pediatric obesity in SWP. Findings from this study indicate that we successfully extended the reach of our program by recruiting participants from communities outside the original catchment area to participate in the Research Registry. Notably, 106 of the 114 participants recruited from new zip codes were from areas outside of Allegheny County and 58% were from areas beyond the surrounding counties. Thus, we continue to enroll participants from additional areas of SWP.

We largely attribute the geographical expansion of the Registry to our efforts to promote our weight management program throughout SWP. Our wellness staff has introduced numerous community-based pediatricians to our program, and, in turn, we have experienced an increase in patient referrals. We have established working relationships with physicians in three community-based practices. In addition to our CHP WMWC, our wellness staff treats patients at a satellite clinic in Johnstown, PA (located east of Pittsburgh in Cambria County). A partnership has also been formed with a community-based pediatric office in Canonsburg, PA (located southwest of Pittsburgh in Washington County). Dietitians from the CHP WMWC have been providing nutritional counseling to pediatric patients at the Canonsburg practice for the past year. However, other aspects of the WMWC protocol have not been implemented at the practice. Thus, patients treated at the Canonsburg practice are not consented for the Registry. An additional partnership was recently formed with a pediatric office in Jeannette, PA (located east of Pittsburgh in Westmoreland County). Discussion among WMWC investigators and Jeanette-based pediatricians resulted in plans for extending the WMWC protocol into routine visits in the future. Interestingly, even though our services have extended to the community, we have found that many families prefer to travel to the WMWC in Pittsburgh to seek weight management treatment. In fact, even after explaining to patient referrals living in the Johnstown area that a satellite facility is available to them, they still often choose to travel to the Pittsburgh clinic. Ideally, we would like to see community-based pediatricians adopt our program as a mechanism for educating and treating childhood obesity within their respective practices. We continue to work toward realizing this goal.

Military Populations

Additional efforts to geographically expand the Research Registry included implementing and recruiting patients into the Registry at WHMC. The implementation process and recruitment outcomes are described in this section.

Methods

Project investigators at UPMC and AF agreed to implement the Research Registry at the SAMPC Pediatric Wellness Center as part of this award. The protocol was submitted to and approved by the University of Pittsburgh (UP) Institutional Review Board (IRB), the WHMC IRB, and SGE-C (formally SGRC). Steps taken to gain IRB approval for the WHMC Research Registry were as follows:

Step 1: Prepare WHMC IRB application and supporting documents.
Step 2: Prepare and submit UP IRB application with attachment of WHMC IRB materials.
Step 3: Upon approval of UP IRB, submit WHMC IRB application to WHMC review board.
Step 4: Upon approval of WHMC IRB, submit the WHMC IRB application and support documents to the UP IRB and gain approval for any modifications made by the WHMC IRB.
Step 5: Submit IRB approved documents to SGE-C for final review and approval.

Project staff consulted Dr. James Barker, former WHMC IRB director, to prepare the WHMC IRB application and supporting documents. Dr. Barker advised submitting the Research Registry protocol in the form of a "data repository" with a focus on the development of the Research Registry, i.e., consenting patients at the SAMPC Pediatric Wellness Center and entering their medical information into a research database. Dr. Barker suggested that related research activities, such as retrospective studies on data in the database or prospective studies of clinical outcomes, be submitted as separate protocols after implementation of the Research Registry. In turn, the research protocol and associated documents (i.e., informed consent form) were prepared according the WHMC data repository guidelines.

Subsequently, a research protocol was prepared for the UP IRB, the IRB of record for UPMC research protocols. A similar protocol, following UP-specific guidelines, was developed for the UP IRB and submitted, along with the WHMC protocol and supporting documents, using the UP electronic submission form called OSIRIS. Dr. Dale Ahrendt, the primary investigator of the WHMC Research Registry, and Jodi Krall, co-investigator, submitted the research protocol to the UP IRB on 09 January 09. SGE-C provided concurrence on 2 September 2009.

Results

The Research Registry was implemented at WHMC on 14 September 2009. The SAMPC Pediatric Center staff members were trained on how to implement the Research Registry using the following IRB-approved methodology.

Participants

All children and youth presenting to the SAMPC Pediatric Wellness Center are offered participation in the Research Registry. The Center patient population includes children and youth of either sex and any race or ethnic background, aged 2-22 years, generally with a BMI $\geq$ 85th percentile for age and sex.

Description of Research Activities

Participation in the SAMPC Pediatric Wellness Center Research Registry is limited to placement of patient-subject medical information in the Research Registry. The information will be used for retrospective research studies directed at childhood obesity and/or for future research studies involving childhood obesity. Retrospective and future research studies involving information contained in the Research Registry will require separate IRB approval.

- Patients (and their legal guardians) seen at the SAMPC Pediatric Wellness Center are asked by Center staff to provide written informed consent to allow patients' past, current, and future medical record information to be placed in the Research Registry. Medical information placed in the Research Registry relates directly or indirectly to childhood obesity.
    - Patients (and their legal guardians) are asked to provide their permission for the use of medical information for retrospective research studies directed at childhood obesity; such research to be conducted by the SAMPC Wellness Center investigators.
    - Patients (and their legal guardians) are asked to provide their permission to allow SAMPC Pediatric Wellness Center investigators to review this information to determine if the patients-subjects may be eligible for participation in future research studies being conducted by Center investigators.
    - Patients (and their legal guardians) are asked to provide their permission to allow SAMPC Pediatric Wellness Center investigators to contact them (i.e., based on a determination of their potential eligibility) to ascertain their interest in participating in future research studies being conducted by Center investigators.
    - Note: Patients-subjects contacted for participation in future research studies being conducted by SAMPC Pediatric Wellness Center investigators will undergo a separate informed consent process for each such research study.
- Patient-subject medical information will be stored electronically within the Research Registry. Identifiable information (i.e., names, social security numbers, and medical numbers of patients-subjects) will be deleted from their stored medical information and replaced with a linkage code. Access to patient-subject medical information contained within the Research Registry will be restricted to SAMPC Wellness Center investigators.
    - Information linking the linkage codes to the patients'-subjects' identifiable information (i.e., names, social security numbers, and medical record numbers) will be stored in a secure location separate from the medical information. Access to the information lining the linkage codes with patients'-subjects' identifiable information (i.e., names, social security numbers, and medical record numbers) will be granted only to SAMPC Pediatric Wellness Center investigators on a need-to-know basis as approved by the Principal Investigator (i.e., Dale Ahrendt) of the Research Registry. Access to the information linking the linkage codes with patient-subject identifiers shall be documented.
    - Patient-subject medical record information will be stored in the Research Registry for an indefinite period of time.
- The Principal Investigator (Dale Ahrendt) of the Research Registry must approve all retrospective research studies being conducted by SAMPC Pediatric Wellness Center investigators using medical information contained within the Research Registry. Such approval shall be obtained after research studies have received IRB approval and prior to providing investigator access to the Research Registry information; shall be based upon considerations of scientific inquiry and validity; shall be granted only for research studies related to medical conditions associated with childhood obesity; and shall be documented.
- Patient-subject medical record information contained within the Research Registry may be provided to secondary research investigators (i.e., research investigators who are not affiliated with the SAMPC Pediatric Wellness Center). However, prior to its provision to any secondary investigator, the information shall be de-indentified. The SAMPC Pediatric Wellness Center shall require secondary investigators to obtain IRB approval of an "exempt" research application prior to its provision of de-identified information to the secondary investigator.
- Patients-subjects will not be informed of the results of retrospective research studies involving the use of their medical record information contained within the Research Registry.
- Access of the SAMPC Pediatric Wellness Center investigators to information contained within the Research Registry for the purpose of determining if patients-subjects may be eligible for participation in a research study shall be granted only upon evidence of IRB approval of the research study for which access is being requested. Access of SAMPC Pediatric Wellness Center investigators to the Research Registry for the purpose of identifying patients-subjects for participation in a research study shall be documented.

<u>Informed Consent</u>

- Patients (and their legal guardians) are approached by a member of the SAMPC Pediatric Wellness Center staff and are asked to review a copy of the informed consent prior to their scheduled visit. During the course of the medical care visit, a Center staff member reviews the informed consent form with patients (and their legal guardians) and addresses any

questions or concerns prior to obtaining written informed consent for participation in the Research Registry. A Center staff member also addresses any future questions or concerns of patients-subjects regarding the Research Registry.

- This aforementioned process is deliberately set up to ensure that patients (and their legal guardians) have sufficient time to decide whether to participate in the Research Registry and to minimize the possibility of coercion or undue influence. In addition patients (and their legal guardians) are granted additional time to consider participation upon request. Patients (and their legal guardians) may request to revisit Research Registry participation /consent at a future appointment. Furthermore, patients (and their legal guardians) are informed that their participation is not a requirement for receiving clinical care at the SAMPC Pediatric Wellness Center and that they are under no obligation to participate in the study.
- Patients who are less than 18 years of age require permission from their legal guardian to participate in the Research Registry. Child patients, who are able, must also provide assent for participation. This is obtained and documented in the informed consent document. If assent is not obtained from the child patient when they first enroll into the Research Registry (due to the child's inability to assent due to age/inability to understand), ability to assent will be reassured at each interaction until assent is obtained. The informed consent document will be reviewed prior to each visit for child patients who have not provided assent for participation.
- Child patients who turn 18 years of age during the course of the study will be reconsented as adults and will be asked to sign a new informed consent form. Level of consent (non-assent, assent, or continued consent as an adult) will be re-evaluated by the study investigators prior to each scheduled appointment in order to determine if further measures need to be taken to update the consent process for each patient.
- If a patient-subject chooses to withdraw from the Research Registry, the patient-subject information obtained up until the point of withdrawal will be kept with the exception of linkage codes (i.e., codes linking personal identifiers and research data), which will be destroyed (shredded/deleted). No new information will be collected after the point of withdrawal from Research Registry participation.

Data Safety and Monitoring

- Secured long-term retention of patient-subject information will be employed to ensure research patient-subject confidentiality. Direct patient-subject identifiers (i.e., name, social security number, medical record number) will be removed from information stored in the Research Registry. Information linking codes (i.e., linkage codes) assigned to the Research Registry information with direct patient-subject identifiers will be secured in a separate location on a double password protected computer in a locked office. In addition, access to information contained within the Research Registry will be limited to SAMPC Pediatric Wellness Center investigators and their designated staff.
- The principal investigator (Dale Ahrendt) must give prior approval for any access of Center investigators to the database linking the Research Registry to participant direct identifiers. Access of Center investigators to the Research Registry for the purpose of conducting retrospective studies or for identifying potential subjects for participation in a research study shall be granted only upon the provision of documentation that the IRB has approved the respective research study. At the time of annual University of Pittsburgh IRB renewal, a list of studies conducted using the Research Registry will be submitted to the IRB. In addition, any unauthorized access to medical record information contained within the Research Registry or to the database linking the Research Registry information to participant direct identifiers shall be reported to the IRB. The principal investigator (Dale Ahrendt) will regularly monitor the study process, including ensuring that access to research data and documents is restricted to appropriate persons involved with this research.

Recruitment of Participants into the Research Registry

As previously mentioned, all patients presenting to the SAMPC Pediatric Wellness Center are eligible to participate in the Research Registry. Since implementation of the Research Registry on 14 September 2009, 95 patients have been seen at the Center and all have been approached to participate in the Registry. Of these patients, 92% (n=87) have consented to participate in the Registry and 8 have refused participation.

Summary

The Research Registry serves an important role in our efforts to address pediatric obesity in the military healthcare beneficiary population. Of primary significance, the Registry enables us to monitor the impact of our weight management program across time. In addition, the Registry can be utilized to gain knowledge about the reach of our program in terms of demographics, health statistics, and geographical location, as well as the association between parental deployment and child weight status.

The process to obtain IRB approval was time-intensive and took much longer than we originally anticipated. It should be noted that this is the first IRB protocol that we submitted for pediatric research at WHMC. Although the IRB process delayed commencement of Registry activity, it will not significantly impact the quantity and quality of information that we will be able to include in the Registry. This is due to the fact that we are able to consent patients at initial and follow-up visits and upon consent, have access to all patient medical information recorded prior to consent. The total number of unique patients seen at the SAMPC Pediatric Wellness Center to date is 207; of these, 95 have visited the Center within the 3-month period since the Research Registry has been implemented. Thus, we have already invited 46% of all patients to participate in the Registry. Furthermore, we have been extremely successful at recruiting patients into the Registry, with a recruitment rate of 92% as previously stated. If this recruitment rate continues, we can be assured that the patient medical information contained in the Registry is representative of the SAPMC Pediatric Wellness Center patient population and will provide meaningful data regarding the causes and treatment of childhood obesity of military dependents.

3. ADULTS

PRIMARY PREVENTION

In the United States (US), approximately 24 million people have diabetes while another 57 million are reported to have "pre-diabetes," increasing their risk for developing type 2 diabetes (T2D) as well as cardiovascular disease (CVD) [**1**]. Moreover, approximately 65% of US adults are overweight or obese. [**2**]. Research indicates that the presence of overweight defined by Body Mass Index (BMI) of > 25 kg/m^2 and abdominal obesity (AO) defined by a waist circumference (WC) of > 40 inches in men and > 35 inches in women are most strongly associated with metabolic abnormalities (MetS) and consequently predict those at risk for obesity-related disease like diabetes (T2D) and cardiovascular disease (CVD) [**3** - **6**]. MetS is a cluster of risk factors that include AO, elevated triglycerides, blood glucose (BG) and blood pressure (BP) as well as low HDL cholesterol [**7**]. Improper nutritional practices and physical inactivity are major causes of MetS [**8**].

Findings from the national Diabetes Prevention Program (DPP) demonstrated that people at risk for T2D who participated in a lifestyle intervention (developed by the investigators at the University of Pittsburgh), decreased their chance of progressing to diabetes by 58% [**9**]. With its initial funding from the Department of Defense (DOD), the original DPP investigative team from the University of Pittsburgh Diabetes Institute (UPDI) established the Diabetes Prevention Support Center (DPSC) and modified the DPP curriculum, further referred to as mDPP, to serve as a user-friendly program to be translated into communities. The DPSC team successfully trained, implemented and evaluated the mDPP, further referred to as the Group Lifestyle Balance (GLB) program in a number of urban [**10**], rural and military communities.

Civilian Populations

In an effort to implement primary prevention work through a variety of modalities in urban and rural communities, the UPDI and the DPSC completed and tested the effectiveness of the following objectives:

1. Using Lay Health Workers (LHW) to support GLB program;
2. Decreasing barriers to engaging people in screening effort by using BMI and WC as criteria to identify individuals for the intervention with follow-up assessment of metabolic syndrome;
3. Media based (DVD) approaches to diabetes and primary prevention.
4. Tracking of DPSC and PARC services.

This report summarizes the evaluation of the aforementioned methodologies.

Objective 1. Effectiveness of lay health workers supporting GLB Program

Background

With FY '04 and '05 funding, we used community-based screening to identify people at risk for T2D and CVD to participate in a community based GLB program. Lay Health Workers (LHW), functioning as community peers and staff extenders, were engaged to serve as an integral part of the GLB program. Given the epidemic of obesity related to T2D and CVD in the US, the need to address low-cost means to help support and extend the services of higher cost health professionals who traditionally train and support people at risk in community-based lifestyle programs must be explored. As part of our primary prevention project with FY '06 funds, we evaluated at-risk participant's satisfaction with the LHW.

Methods

LHW training was experiential in nature and under the close supervision of the principal investigator (PI) and other professional staff. The LHW assumed a dual role of LHW *and* participant during the first GLB program offered in the study. This experience helped them to identify and practice the tasks to be performed by the participants and provided hands-on learning of the GLB content. Training on research methods was provided by the PI. Strict oversight of research tasks was provided by the PI. In addition, to enhance their skills for providing ongoing support to participants, the LHW attended an 8 hour training on Motivational Interviewing provided by an expert in the field from the University of Pittsburgh and Western Psychiatric Institute. In order to determine if a LHW participating as part of a team with a dietitian and an exercise physiologist are able to effectively support the training and ongoing needs of the participants, the participants were surveyed with an 11-item questionnaire to determine their satisfaction with the LHW.

Results

- Two LHW were engaged and trained to support the GLB program participants
- 114 participants were enrolled in the program (87.1% female, 60% non-white, 93% with BMI ≥ 30 kg/m^2). Of those enrolled, 74.5% (n=85) completed the LHW questionnaire. All participants strongly agreed (82.3%) or agreed (17.7%) that the LHW were helpful during class sessions; however, only 36.5% (31) sought LHW advice outside of class.
- 70.6% of participants sought support from LHW at least once during the program.
- Of those, 78.3% (47) reported being helped by the LHW emotionally; 90% (54) reported being helped with general food/nutrition information; and 80.3% (50) with exercise information.
- 33.8% of participants reported feeling "much more comfortable" asking the LHW questions as compared to the dietitian or exercise specialist; while 60% (51) reported feeling equally as comfortable with the LHW and the professional staff.

Summary

This is one of the first studies to examine the effectiveness of using LHW in a community-based primary prevention program. We found that integrating LHW into a primary prevention team is feasible and valuable to participants. Participants in the GLB program reported satisfaction with the assistance of LHW and found them to play an important role in the GLB program.

We recognize that we had a small participant and LHW sample size. We have yet to investigate the association between LHW satisfaction and participant clinical outcomes. Since the topic of LHW feasibility is novel, there are no validated questionnaires specific to LHW so we were left to develop the satisfaction questionnaire.

LHW are often identified as community members who have taken an active role in their own health care. Relying on people in the community who are most often volunteers and require limited training (in that their role is limited to providing support), implicates that this LHW concept is highly generalizable. This is a particularly useful strategy for rural, underserved areas, and military communities where resources are often limited. LHW may be a valid option for extending services of higher cost healthcare professionals.

Objective 2. Compare use of BMI and WC versus full standard MetS when screening at risk individuals for diabetes and CVD

Background

With FY '04 and '05 funding, we examined community-based screening for MetS and BMI and a lifestyle intervention. As screening for MetS requires an eight hour fast, GLB program researchers found this to be an impediment to recruitment in a community represented by a predominately blue collar and service sector work force whom often begin work before 7:00 a.m. and/or rotate shifts. While the GLB program was well accepted by those enrolled during FY '04 and '05, researchers believed even more people would participate if screening were made simpler.

As another component of our prevention FY '06 funding, we examined the use of less intrusive techniques for community screenings to increase the numbers and provide a more efficient way of identifying and recruiting participants for the program. Historically, community-based screenings for T2D and CVD risk relied on paper-based risk scores and/or fasting blood samples. Other non-invasive, cost-effective measurements of risk, however, need to be examined to identify those at risk in community settings, where resources may be limited. Recent research demonstrates that abdominal obesity (AO) is most strongly associated with metabolic abnormalities and may predict those at risk for T2D and CVD. Therefore, a non-fasting screening for eligibility, using BMI and WC as determinants of eligibility became the FY '06 screening protocol. MetS was subsequently assessed once a participant enrolled in the intervention.

Methods

Participants for these analyses were part of a community-based risk screening initiative that took place between 2005 and 2008. 638 individuals were screened for eligibility for a GLB program. Eligibility criteria were: ≥ 18 years of age, BMI ≥ 25 kg/m2 and MetS as defined by the Adult Treatment Panel III (ATP III).

Receiver operating characteristic (ROC) curves, adjusted for age, race, and gender were constructed to assess discrimination between AO (waist circumference > 40 inches in males and > 35 inches in females) and other components of MetS (blood pressure ≥ 130/85 mmHg; glucose ≥ 100 mg/dL; triglyeride levels ≥ 150 mg/dL; and HDL cholesterol < 40 mg/dL in males and < 50 mg/dL in females). The primary outcome was risk which was defined as having MetS.

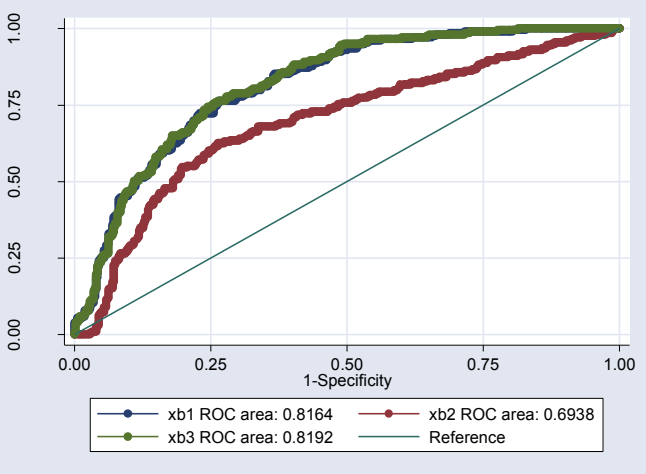
Results

- Mean age was 53.3 ± 15.4 years and three quarters (75.6%, n=482) of the population were female and 26.9% (n=170) were non-white.
- 31.8% (n=203) had MetS; of those with MetS, 89.2% had abdominal obesity, 82.3% had abnormal HDL levels, 66.5% had hypertension, 52,7% had triglycerides ≥150 mg/dL, and only 42.4% had a glucose ≥100 mg/dL.
- In all models, the area under the ROC curve (AUC) was highest for WC (0.82) and WC+ a clinical indicator (0.82, 0.88, 0.88, 0.84 models 1-4 respectively).
- When WC was compared to each clinical indicator, the AUC was significantly higher for WC compared to fasting glucose (0.82 vs. 0.69, p<0.0001) and WC compared to hypertension (0.82 vs. 0.69, p<0.0001).
- Adding clinical indicators did not significantly increase the AUC in any of the models.
- AUC and their corresponding 95% confidence intervals are presented in figures 1-4 below.

Figures 1-4. Area under the ROC Curve for WC and Clinical Indicators in Identifying MetS in an Urban, Underserved Community (n=638)

Figure 1. WC and Fasting Glucose

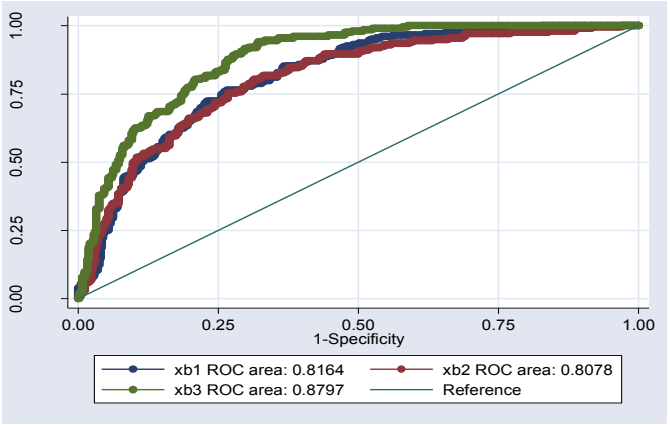
Figure 1 represents the Receiver Operating Characteristic (ROC) curve to assess the discrimination between WC and fasting glucose. This model was adjusted for age race and gender. As noted in the table, the area AUC was highest for WC (0.82) and WC + fasting glucose (0.82). When WC was compared to fasting glucose, the AUC was significantly higher for WC than for fasting glucose (0.82 vs. 0.69, p<0.0001).



	AUC	95% CI
Waist circumference (xb1)	0.82	0.78, 0.85
Fasting Glucose (xb2)	0.69	0.65, 0.74
Waist circumference + Fasting Glucose (xb3)	0.82	0.79, 0.85

Figure 2. WC and Triglyceride Levels

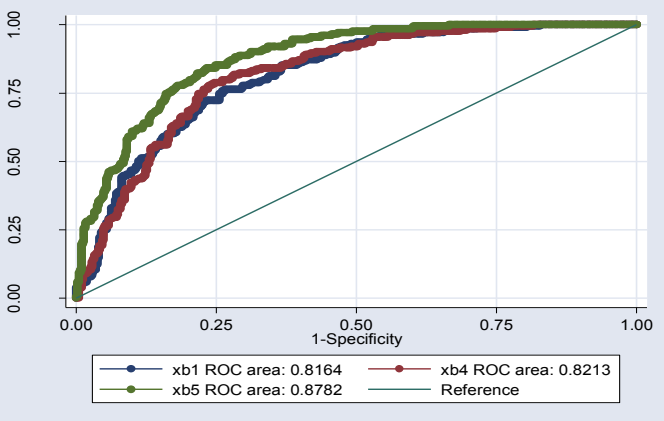
Figure 2 represents the ROC curve to assess the discrimination between WC and triglyceride levels. This model was adjusted for age race and gender. As noted in the table, the AUC was highest for WC + triglyceride levels (0.88). When WC was compared to triglyceride levels, the AUC was not significantly higher between the two indicators (0.82 vs 0.81, p=0.73); however, when WC was added to triglyceride levels, the AUC increased significantly (0.88, p<0.0001).



	AUC	95% CI
Waist circumference (xb1)	0.82	0.77, 0.84
Triglycerides (xb2)	0.81	0.77, 0.85
Waist circumference + Triglycerides (xb3)	0.88	0.85, 0.91

Figure 3. WC and HDL Cholesterol

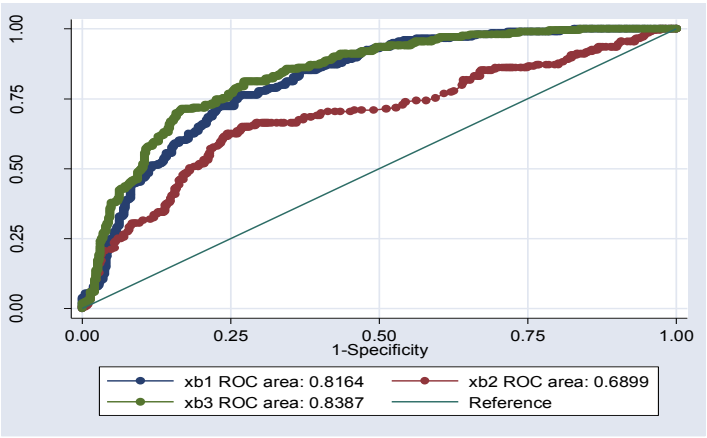
Figure 3 represents the ROC curve to assess the discrimination between WC and HDL cholesterol levels. This model was adjusted for age race and gender. As noted in the table, the AUC was highest for WC + HDL levels (0.88). When WC was compared to HDL, the AUC was not significantly higher between the two indicators (0.82 vs 0.82, p=0.83); however, when WC was added to HDL levels, the AUC increased significantly (0.88, p<0.0001).



	AUC	95% CI
Waist circumference (xb1)	0.82	0.78, 0.85
HDL cholesterol (xb4)	0.82	0.79, 0.85
Waist circumference + HDL (xb5)	0.88	0.85, 0.90

Figure 4. WC and Hypertension

Figure 4 represents the ROC curve to assess the discrimination between WC and hypertension. This model was adjusted for age, race and gender. As noted in the table, the AUC was highest for WC + hypertension (0.84). When WC was compared to hypertension, the AUC was significantly higher for WC than for hypertension (0.82 vs. 0.69, p<0.0001).



	AUC	95% CI
Waist circumference (xb1)	0.82	0.78, 0.85
Hypertension (xb2)	0.69	0.64, 0.74
Waist circumference + Hypertension (xb3)	0.84	0.81, 0.87

Summary

We recognize that the analyses and results that examine the positive predictive relationship between WC and MetS are not well established in the literature. Therefore, our results may be limited to other populations that may not have the same characteristics as our sample. Additionally, subjects for these analyses were those with a documented BMI measurement. Thus, it is inherent that our sample may be at higher risk and thereby overestimate the ability to predict MetS. We also appreciate the other limitation of this study in that particpants were members of urban, underserved communities near Pittsburgh, PA. Therefore, their characteristics may not be generalizable to other populations. The predictive validity of our ROC model has not been established in any population other than in this sample.

Despite the limitations, our results suggest that WC is an effective method for identifying those at risk. Methods like this may be a more acceptable mechanism for screening. Measuring WC to determine T2D and CVD risk is a simple, non-invasive method that can be performed at the point of service in a community setting. Using WC as a proxy for T2D and CVD risk, because of its ease in performance, offers potential to capture a larger pool of people who may benefit from risk reduction interventions.

Further development and examination of this concept may allow healthcare payers to identify patients who may be potential candidates for risk reduction interventions without having to obtain and/or retrieve cumbersome clinical data from administrative claims.

Objective 3. Evaluate impact of DPSC on participating sites and demand for DPSC services

Background

In an effort to expand their services to new sites, the faculty of the DPSC provides health professionals both local and off-site GLB training workshops. Additionally, the faculty of the PARC realized a web-based program would provide an opportunity for other researchers to access extensive and easily accessible subjective and objective assessment tools to improve the quality of physical activity efforts in future investigations and programs.

Expansion of DPSC and PARC Services to Additional Populations

The DPSC tracks request for services, including preventionist training and "train the trainer" on an ongoing basis.

The DPSC trained 89 health care professionals during FY 06. This included an off-site training workshop for health care professionals at Wilford Hall Medical Center (WHMC), San Antonio, TX, as well as on-site training of several other military personnel and health care professionals from other DOD supported projects. Since 2004, a total of 398 individuals have attended training workshops.

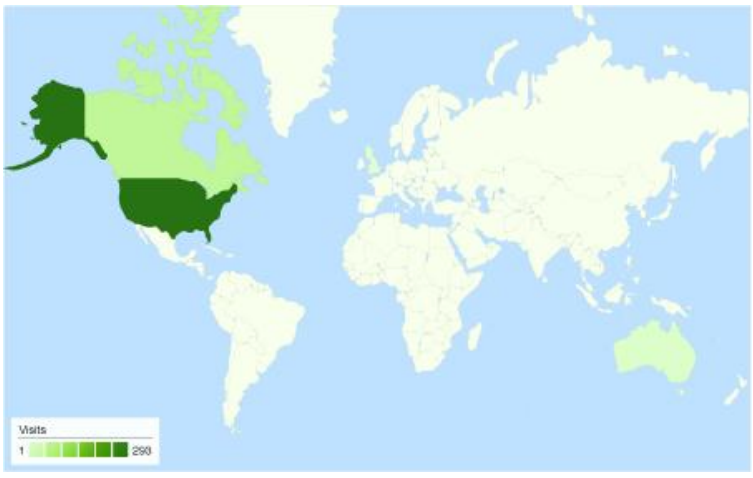
DPSC continues to use the train the trainer protocol. The following individuals have been formally trained as "Train the Trainers":

- Donna Wolf, PhD
- Tanya Crail, MS, RD
- Mim Seidel, MS, RD

The PARC website is available for use. PARC tracks requests ("hits") for services (Figure 5). A broad announcement regarding the website "live" status was done on November 6 2009. Visit the PARC website at: www.parcph.org.

Figure 5. PARC-PH Web-Site Visits between September 20 and November 30, 2009

293 queries during this time frame came from the US. In addition, the following queries were received from international colleagues for a total of 370 visits: 52 from Canada; 9 from Australia; 4 from Hong Kong; 2 from the United Kingdom; 1 each from Germany; South Africa; Thailand; and 2 from other (not set).



Summary

The DPSC and PARC continue to expand training opportunities and tools located on the PARC website.

Objective 4. Effectiveness of media-based approach to diabetes and primary prevention

Background

Based on their experiences implementing the GLB with FY '04/'05 funds, the DPSC determined that an alternative methodology that does not require on-site participant attendance for 12 weeks of GLB classes could potentially be a useful strategy in reaching additional at risk populations. They determined in collaboration with the military that this could be particularly useful for military personnel who are often in transition and for whom long-term group attendance may not always be feasible. The DPSC subsequently partnered with the AF CEMM to develop a multi-media version of the GLB program in both DVD and CD. The GLB-DVD is designed to lead to weight loss and reduced diabetes and CVD risk

Methods

This project aimed to evaluate the effectiveness of the GLB program delivered traditionally, as well as the DVD based Group Lifestyle Balance (GLB-DVD), on a long-distance basis through a primary care practice in California. The two specific delivery methods of the GLB intervention that were studied are a) the provision of the traditional GLB by a trained preventionist with long distance support from the DPSC and b) the provision of the media-based GLB-DVD with structured weekly contact with the DPSC. Efficacy was assessed for both interventions by pre- and post-intervention measures of weight, as well as the achievement of the two goals – a 7% weight loss by the end of 12 weeks, and 150 minutes of physical activity per week. Secondary outcomes measured include assessment of the metabolic syndrome and its components (NCEP ATP III) and change in BG and HbA1c.

Non-diabetic individuals age 18 and older (at enrollment) whose (BMI) was ≥25 kg/m2 and who exhibited pre-diabetes and/or at least three of five components of MetS were eligible to enroll in the GLB program. Individuals with a previous diagnosis of diabetes, women who were pregnant or lactating, or anyone participating in any other similar research study were not eligible for this project. All study participants were able to read and understand English, as the program is currently not available in other translations.

The preventionist in the practice was a health care professional who completed the two-day GLB training workshop and also received training in the collection of outcome measures. The preventionist conducted the recruitment and follow up for all participants enrolled in both GLB and DVD-GLB. The DPSC preventionist providing support for the GLB-DVD participants was also a health care professional who completed GLB training and had prior experience in delivery of the GLB program.

Patients identified as meeting the criteria for participation in the GLB program were referred to the program by their physician. Inherent in the provision of referral was the physician's ascertainment that the participant was physically and psychologically appropriate for a lifestyle change program which includes recommendations for moderate physical activity, e.g. brisk walking, for 150 minutes per week. After completing informed consent, participants chose Group GLB or GLB-DVD delivery. All participants attended an initial baseline assessment visit prior to beginning the GLB program as well as a post-intervention assessment. Measures collected include medical and lifestyle history, height, weight, BP, WC, fasting BG and lipids, and HbA1c. In addition, the EQ5D Survey, a standardized tool for measuring overall health including psychosocial indices, was completed by participants at the baseljne and post-assessment visits. Group GLB Delivery: The 12-session goal-based, behavioral lifestyle curriculum was administered by the primary care practice preventionist in two groups over approximately 15 weeks. Each participant received a lifestyle intervention manual and workbook, self-monitoring books for keeping track of food and physical activity, a pedometer, and a chart for self-monitoring their weekly weights over the course of the treatment program.

GLB-DVD Delivery: The DVD-GLB consists of a series of taped sessions of a staged GLB group following a script which was developed to closely follow the original GLB. Instruction concerning the use of the DVD-GLB and materials was provided at commencement of the intervention. Participants were instructed to view one session each week and to complete the assignments; each month the participant was asked to return their DVD via postage-paid mail to the DPSC

and another DVD for the next month was sent to the participant. During delivery of the 12-session DVD there was at least weekly contact with the DPSC via phone to report such things as weight, keeping track, questions about the program, etc. All participants in the DVD-GLB received the same materials and tools that were given out in the Group GLB program.

Data Analysis and Data Monitoring

Based on the weight loss seen in the Screening, Training, Education and Prevention Service of the University of Pittsburgh (STEP UP), and similar to the trend seen in the DPP at approximately 3 months, it was estimated for alpha=0.05 and at least 20 subjects in either group, we would have approximately 96% power to detect a 3.5% weight loss in each intervention group and >99% power to detect a weight loss of 7%. It was planned that additional subjects would be recruited to ensure the number needed to support the power calculation, up to a total of 50 participants. Analyses were conducted by both intention to treat (using last observation carried forward methodology for participants who did not attend the post assessment visit) as well as per protocol for those that attended both the baseline and post-intervention assessments.

Results

A total of 48 participants enrolled (34 female, 14 male). Participants were primarily white (83%), with a mean age of 59.7 years. The mean baseline BMI, glucose, triglyceride, and blood pressure levels were 34.1 kg/m^2, 102.4 mg/dl, 146.7 mg/dl, and 124/72 mm/Hg respectively. Twenty-six participants chose face to face group and 22 chose DVD delivery mode. A higher proportion of males chose GLB-DVD than GLB-Group (41% vs. 19%,NS); a significantly higher proportion of those who chose DVD versus face to face group reported having some college or higher level education (86.4% versus 61.6%, p=0.05). In addition, those in the DVD group had a significantly higher mean glucose (107.6 mg/dl versus 99 mg/dl, p=0.008) but significantly lower HbA1c level (5.8% versus 6%, p=0.04). No other differences in baseline characteristics were noted between the groups.

- Overall mean weight loss was 5.6% and 6.6% for GLB-DVD and GLB-Group respectively.
- Significant decreases in total cholesterol, fasting glucose, HbA1c, systolic and diastolic blood pressure, waist circumference and BMI were noted for those in the GLB-DVD group, while significant decreases in HbA1c, systolic and diastolic BP, WC and BMI were noted for those in the face to face GLB delivery group
- In a per protocol analysis of those completing both the pre and post assessments, for those in GLB-DVD (n=14, 64%), mean weight loss was 8.9% with 10 (71%) reaching 7% and 12 (86%) reaching at least 5% weight loss, while for those in GLB-Group (n-23, 88%) mean weight loss was 7.0%, with 9 (38%) and 17 (71%) reaching at least 7% and 5% weight loss respectively.
- Participant report of completion of physical activity at least three times per week increased significantly in both groups, as did report of self-monitoring of food intake, activity and weight.
- A significant decrease in the proportion reporting problems with mobility was noted between pre and post assessment (24.3% versus 2.7%, p=0.04) for those completing the EQ5D Survey at both visits in both groups combined (n=37).
- In addition, a significant increase in the mean participant self-reported health state score (where 0=Worst Imaginable Health State and 100=Best Imaginable Health State) was noted between baseline and post-assessment in both the DVD-GLB group (+13.7 points, 20.5%, p=0.004) and the face to face GLB group (+8.9 points, 11.7%, p=0.018). A significant decrease in the proportion reporting problems with pain for those in the face to face GLB group was also noted (13% versus 4.3%, p=0.009). No significant changes were noted in self-reported usual activity, self-care, pain/discomfort (DVD-GLB group) or anxiety/depression.

Summary

Results suggest that GLB delivered via DVD was feasible to implement on a long-distance basis and was effective in reducing multiple risk factors for diabetes; it could therefore offer an alternative option for diabetes prevention intervention delivery. Additionally, the GLB program was successfully implemented with long-distance support in the face to face delivery option.

There are several limitations that should be mentioned. This project was conducted in a small group of primary care practice patients in California, thus the results may not be generalizable to other populations. Also, several participants were lost to follow up, particularly in the DVD group. Although reasons for drop out were known for some of the participants, specific follow up regarding this will be helpful going forward. Finally, this project did not include a formal cost evaluation; however, preventionist time involvement was collected and will be analyzed.

Strengths of this project include a prospective design with data analyzed following an intention to treat principle as well as per protocol. In addition, participants were permitted to choose their intervention delivery method, thus following translational research guidelines that are similar to real world processes for implementation.

The results of this project suggest that GLB delivered via DVD was feasible to implement on a long-distance basis and was effective in reducing multiple risk factors for diabetes. In addition, the GLB program was successfully provided with long-distance preventionist support from the DPSC in both face to face group and DVD delivery. In addition to effectively reducing several risk factors for diabetes, participants in both delivery modes demonstrated an increased self-reported health state score.

As we move forward with diabetes prevention on a large scale both nationally and within the military, provision of the GLB delivered in face to face groups with long-distance preventionist support and via GLB-DVD could provide effective options for diabetes prevention intervention delivery.

Military Populations

In an effort to implement primary prevention work through a variety of modalities for AF healthcare beneficiaries, the UPDI and the DPSC completed the following objectives:

1. Determine the effectiveness of web-based tools for primary prevention (VLM)
2. Evaluate the impact of DPSC and PARC on participating sites and the demand for services
3. Determine the effectiveness of media-based approach to diabetes prevention
4. Determine the effectiveness of primary prevention programs implemented at WHMC
5. Determine cost-effectiveness of a primary prevention program implemented at WHMC

Objective 1. Determine the effectiveness of web-based tools for primary prevention (VLM)

Background

Information technology is considered central to improving healthcare quality in light of the rising burden of chronic disease [**11**], and finding ways to utilize information technology for improving the quality of health care delivery is a major challenge facing clinicians and health services researchers [**12**]. However, the Internet has to date played only a limited role in the delivery of preventive counseling, despite its potential for helping overcome the myriad of barriers that deter the routine delivery of evidence-based lifestyle interventions. Counseling for healthy lifestyles is often overlooked in the clinical setting [**13**, **14**], with quality indicators involving counseling or education showing less than 20% adherence [**15**]. Time-limitation [**16**-**18**], a lack of physician training in nutrition counseling [**16**, **17**] and cost [**19**] are barriers to incorporating nutrition and physical activity counseling into routine preventive medicine. A web-based, effective intervention could overcome such barriers by automating and standardizing much of the counseling process, thus potentially minimizing staffing costs while increasing patient convenience. At the same time, it could increase access to patients by releasing constraints posed by scheduling or travel demands.

Our research team previously developed an Internet-based version of the Diabetes Prevention Program's lifestyle intervention, the Virtual Lifestyle Management (VLM) Program. This program was successfully piloted in a group of primary care patients in Pittsburgh, Pennsylvania [**20**]. Its goals include weight reduction of at least 7% of initial body weight and moderate intensity exercise for 150 minutes/week. Targeted weight loss is 1-2 pound per week until goal and maintenance of the reduction. This degree of loss is adequate to improve glycemic control, blood pressure control, and dyslipidemia [**21**]. VLM assists individual participants with establishing appropriate weight loss goals, dietary recommendations (including analysis of current diet), and defining exercise programs.

The curriculum provides standard information about healthy lifestyle, and behavioral techniques for integrating them into daily living. In each lesson, participants provided feedback about how they interpreted the information, and ideas for integrating it into their lives. Lifestyle coaches review these entries weekly, and provided support, feedback about progress, and tips on how to problem-solve around lifestyle barriers. Furthermore, electronic tools aid in the self-monitoring of weight, eating and physical activity, and automated reports provide feedback to referring physicians.

The VLM program was developed and piloted functioning within a health portal in a civilian health care setting. In the current project, our aim was to adapt it to a web-based program to facilitate its use in an outpatient military-affiliated clinical setting, and then to implement and evaluate the web-based version in coordination with outpatient medicine delivery at Wilford Hall Medical Center at Lackland Air Force Base, San Antonio, Texas.

Methods

Telephone versus Secure Portal for Doctor Patient Communication

We evaluated the amount of time needed for health provider staff to communicate with outpatients synchronously (primarily by phone) and asynchronously (primarily via HealthTrak)

Integrate Virtual Lifestyle Management (VLM) Coach into a web-based format to facilitate connectivity to other remote locations.

We worked with a subcontractor, DPS-Health, the software company which the UPMC had hired to program the original Portal-based VLM program. DPS-Health adapted the program to function independently of the web portal environment, as an independent web-based entity. This web-based program has undergone an extensive operational utility evaluation, including assessments or reliability, usability, and security, conducted by the USAF/SGR Test Bed facility at WHMC.

Implement VLM Coach in AF healthcare beneficiary populations and gather information from participants utilizing the VLM Coach.

The University of Pittsburgh investigators worked with Major Mark K. Wallace, MD, Lieutenant Colonel Mark W True, MD and Lieutenant Colonel Jack E. Lewi, MD to plan and carry out the logistics of implementing VLM into the care provided in the WHMC outpatient medicine clinics. Planning was accomplished through a combination of in-person meeting and multiple conference calls. Institutional Review Board Approval for a four-month pilot and evaluation was obtained June 3, 2008. The need for WHMC Test Bed approval was identified approximately two months later, and recruitment was delayed until such testing could be completed. However, in the interim, staff at WHMC were trained in online lifestyle coaching and taught how to collect the evaluation measures. Test Bed approval was obtained on April 8, 2009 and participant recruitment was initiated on the same day, with the first participant orientation session held on June 8, 2009.

Participants were recruited, oriented and encouraged to complete 16 weekly lessons (the original DPP's core curriculum) in order, over their four month intervention period. The VLM curriculum provided standard information about healthy lifestyle, and behavioral techniques for integrating them into daily living. Participants were also encouraged to self-monitor their weight, eating and physical activity using electronic tools within VLM, and to access reputable health resources from its archive. In each lesson, participants provided feedback about how they interpreted the information, and ideas for integrating it into their lives. Each participant's assigned lifestyle coach reviewed these entries weekly, and provided brief electronic messages of support, feedback about progress, and tips on how to problem-solve around lifestyle barriers. The coaches also used electronic messaging to answer any participant questions that arose. University of Pittsburgh investigators met weekly with the lifestyle coaches by phone to answer questions about lifestyle coaching and to monitor the adherence of the participants and lifestyle coaches to the intervention protocols.

Evaluate VLM Coach effectiveness in the AF healthcare beneficiary population at high risk for, or with diabetes (T2D). Improvements in cardiovascular (CVD) risk factor status, health behaviors, and weight will be measured qualitatively and quantitatively via information gained through various modalities

Prior to initiation and at the end of the 16-week VLM enrollment period, each participant met with research staff for a final measurement of weight, blood pressure, cholesterol and fasting glucose, if current information was not already included in their electronic medical record. Participant feedback regarding satisfaction was also solicited at the program's end. Evaluation of the VLM program involved collection of information from multiple sources, including the electronic medical record, VLM records, completion of questionnaires outside of VLM, and study visits.

Results

Telephone versus Secure Portal for Doctor Patient Communication

There are several interesting results from the current work measurement study. These preliminary findings indicate that there may be a difference between the time required to communicate with patients synchronously (primarily by phone) and asynchronously (primarily via HealthTrak)

Specifically, all activities require less staff time using HealthTrak compared with telephone based communication. Particularly, appointment scheduling, medication questions, providing results to patients, and prescription refills require less time when done using HealthTrak as compared to telephone.

Preliminary results have been presented to UPMC executives. UPMC has decided that it makes sense to deploy HealthTrak widely throughout the system. We are finalizing analyses to increase the accuracy of point estimates of differences.

Integrate Virtual Lifestyle Management (VLM) Coach into a web-based format to facilitate connectivity to other remote locations.

The VLM program now functions as an Internet-based program. It has passed the extensive operational utility evaluation, including assessments or reliability, usability, and security, conducted by the USAF/SGR Test Bed facility at WHMC.

Implement VLM Coach in AF healthcare beneficiary populations and gather information from participants utilizing the VLM Coach.

After a series of productive planning meetings and conference calls with WHMC physicians and staff, IRB Approval for a four-month pilot and evaluation was obtained June 3, 2008. The need for WHMC Test Bed approval was identified approximately two months later, and recruitment was delayed until such testing could be completed. However, in the interim, seven individuals (including staff at WHMC as well as UPMC employees; see details below) were trained in online lifestyle coaching. Staff at WHMC were also taught how to collect data for the evaluation. Test Bed approval was obtained on April 8, 2009, and participant recruitment was initiated on the same day, with the first participant orientation session held on June 8, 2009.

As the initial set of recruitment approaches that we had derived by working with WHMC health care providers led to insufficient enrollment, we subsequently sought and obtained IRB approval to expand recruitment techniques, with improved recruitment success. The revised recruitment procedures are based on input from WHMC physicians and staff and included the use of flyers and advertisements posted at Lackland AFB and medical centers/clinics, as well as in military publications (web based and print).The research team also spoke extensively to the health care providers at WHMC, and incorporated their suggestions into the recruitment procedures. Furthermore, health care providers reinforced our original aim to use a referral process that works within the normal work-flow of the clinics (e.g., electronic referrals, as is standard in WHMC clinics), but was not feasible to implement during the time-frame of this study. They also suggested that clinical staff who send patients information about health promotion opportunities and resources as part of their routine work duties should be able to include notice of lifestyle interventions with such information.

At the date of this report, while 30 individuals have been enrolled into the program, only 10 participants have completed the four month intervention. We have gathered baseline and 4-month survey data and physical measurements (blood pressure, body weight), and abstracted selected lab values from the electronic medical record. Three UPMC employees stationed at WHMC have provided the lifestyle coaching for the participants.

Evaluate VLM Coach effectiveness in the AF healthcare beneficiary population at high risk for, or with diabetes. Improvements in cardiovascular risk factor status, health behaviors, and weight will be measured qualitatively and quantitatively via information gained through various modalities

Baseline Characteristics

Among the thirty individuals who were enrolled in the program, the average age was 51.00 (standard deviation; SD = 9.38; see Table 1), with a range of 28-62 years. The sample was one third male, showed racial diversity, and was 40% Hispanic. Half of participants had completed college or earned higher degree. Their average score on the Short Test of Functional Health Literacy for Adults was 34.6 (SD 1.6), with all participants scores in the "adequate literacy" range. Most participants reported no difficulty paying for basics. They had a diversity of prior skill working with computers, with approximately 20% rating their computer skills as "beginner" and 33% as intermediate-level.

The average RAND mental health component score calculated from the SF-36 questionnaire was 44.8 (SD 12.4), with 10% of the sample having a below average score, and 27% of the sample with an MHC in the "concerning" range. This latter cut-point quite accurately predicts people with high symptoms on the Beck Depression inventory (3.5% false rate and 33% false negative rate). Each individual in the concerning range was evaluated by WHMC medical staff, and referred for mental health services if appropriate. Poor physical functioning scores were common at baseline, with 40% of the sample scoring in the concerning range and an average physical health composite score of 42.9 (SD 10.4).

Table 1. WHMC VLM Pilot Program Baseline Description (n=30)

Characteristic		MEAN (SD) or *n* (%)
Age	Years	51.00 (9.38)
Sex	% Female	20 (67)
Race	White	16 (53)
	African-American	8 (27)
	American Indian/Alaska Native	1 (3)
	Other	4 (13)
	Not reported	1 (3)
Ethnicity	% Hispanic	12 (40)
Education	Completed high school/GED	5 (17)
	Some college	10 (33)
	Completed college	9 (30)
	Graduate degree	6 (20)
Health literacy*	Inadequate	0 (0)
	Marginal	0 (0)
	Adequate	30 (100)
Ability to pay for basics	Not at all hard	24 (80)
	Somewhat hard	5 (17)
	Very hard	1 (3)
Self-Reported Computer Skill	Beginner	6 (20)
	Intermediate	10 (33)
	Advanced	12 (40)
	Expert	2 (7)
Smoking	% Current smokers	1 (3)
Weight Status	Overweight (25.0-29.9 kg/m^2)	4 (13)
	Class 1 obesity (30.0-34.9 kg/m^2)	10 (33)
	Class 2 obesity (35.0-39.9 kg/m^2)	8 (27)
	Extreme obesity (≥ 40 kg/m^2)	8 (27)
Major weight-related comorbidities	Diabetes	18 (60)
	Hypertension	20 (67)
	Dyslipidemia	20 (67)
Mental health composite score (SF-36)	Optimal (≥ 53)	9 (30)
	Normal (42-52)	10 (33)
	Below Average (39-41)	3 (10)
	Concerning (≤ 38)	8 (27)
Physical health composite score (SF-36)	Optimal (≥53)	5 (17)
	Normal (47-52)	8 (27)
	Below Average (43-46)	5 (17)
	Concerning (≤ 42	12 (40)

* S-TOFHLA (Short Test of Functional Health Literacy for Adults) measures functional health literacy.A score of 0-16 indicates inadequate literacy, 17-22 indicates marginal literacy, and 23-36 indicates adequate literacy.

Program use

Two participants have withdrawn from the program. Among the remaining 28 individuals, who have been enrolled for varying amounts of time, as of December 9, 2009, 57% have logged in within the last 30 days; 57% have completed at least 5 lessons and 32% have completed at least 9 lessons. Among the 10 individuals who have completed their four months of enrollment, 40% last logged in after only one month of use, while 40% continued to log into VLM for at least 3 months. Half completed at least 5 lessons and 30% completed $\geq$ 9 lessons.

Weight and Blood Pressure

Average weight change among the initial 10 individuals completing the program was 0.77 kg with a wide 95% confidence interval (95%CI) that reflects the very small sample size (-5.44 kg, +6.34 kg). Systolic blood pressure dropped, on average by 2.7 mm Hg, again with a wide confidence interval (95%CI: -16.0, +19.0). Average diastolic blood pressure change was minimal (+0.7 mm Hg; 95%CI -12.0, +18.0).

Participant Satisfaction

To date, surveys have been completed by 8 of the 10 participants who have completed the program. Of them, when asked if the program was easy to use, 6 agreed and 2 were neutral. When asked if they were satisfied with the program, 5 strongly agreed and 3 were neutral.

Summary

In this project, we have successfully disengaged the VLM program from a Portal environment, so that it functions as independent web-based software, with reliability, usability and security features consistent with USAF Test Bed parameters. The web-based program was then implemented in coordination with outpatient clinical care at WHMC. We feel that close communication with WHMC physicians and other health-care staff was essential in promoting physician referrals and patient interest, as were our efforts to utilize normal clinical referral and physician feedback mechanisms as well as normal channels of communication about clinical resources as much as possible. In addition, promoting the program through a variety of print and electronic media was a useful recruitment approach.

In this military population, we found that individuals with a wide range of ages, gender and racial/ethnic backgrounds were referred and enrolled into the program. While they showed diverse educational backgrounds and prior computer experience, overall the participants were literate and most had no difficulty paying for basics. Many of those individuals who were referred and enrolled showed quite low mental health composite scores, suggesting a relatively high likelihood of depression in this population. This could be related, in part, to their high body weight. The fact that nearly half (40%) showed low levels of physical functioning may also reflect their obesity, and highlights the health risk present among the obese primary care population.

Although there was variation in program use, a sizable proportion of the enrolled individuals have shown prolonged use of the software and completion of a substantial proportion of the curriculum. Furthermore, most of those who responded to the patient satisfaction surveys had positive responses. However, there was no clear effect on body weight or blood pressure in this sample of 12 individuals.

Limitations

Interpretation of the outcome data (including program use, health measurements and satisfaction) from this pilot is problematic due to the extremely small sample size. However, as the purpose of a pilot study is to understand the feasibility, potential benefits and challenges entailed by implementing a program, we were able to fulfill those goals. Regarding the outcomes data, it is possible that the program did not function as well in the military setting as it did in the earlier pilot among civilian primary care patients in PA. Clearly, there are many differences between the populations which could account for such a difference, such as cultural differences in food and physical activity norms between the two regions, climate differences (most participants enrolled and were encouraged to increase their physical activity during an extremely hot summer in Texas), or factors specific to a military population (e.g., during a time of war, individuals affiliated with a military medical center are likely to face diverse stressors and improvements in diet and physical activity may not be a priority at that time). In addition, the use of remote program oversight may promote less favorable results. It is also possible, that a web-based approach is less effective than a portal-based approach, although

this seems unlikely as the program was coordinated with clinical care in both pilot settings. Alternatively, it is possible that the average effectiveness was similar between the two populations, but the presence of individual variation that is always found in weight loss prohibits the detection of an effect with such a small sample size. The uncertainty about effectiveness and positive response to VLM from staff, providers and participants suggests that further experience with VLM in the WHMC setting is warranted to better understand its effectiveness in this patient population.

Recommendations

- Continue use of VLM as a clinical program at WHMC to better determine whether it adds value to the health care of individuals with diabetes or at high risk for developing diabetes
- Assess program effectiveness, participant satisfaction, and feedback from health care providers.

Objective 2. Evaluate the impact of DPSC and PARC on participating sites and the demand for services

Background

The DPSC provides to health professionals both local and off-site GLB training workshops. The Physical Activity Resource Center (PARC) uses a web-based program to provide easily accessible subjective and objective assessment tools to improve the quality of physical activity efforts in investigations and programs.

The DPSC and PARC agreed to provide training for the GLB program and expand PARC resources for military use. We provided workshops on the GLB and enhanced resources for PARC.

Description of Services Provided

GLB Training Workshops

July 2008

DPSC conducted a GLB training workshop at WHMC; 25 healthcare providers attended. The healthcare providers in attendance represented Lackland, Randolph and Goodfellow AFB.

January 2009

Ms. Tanya Crail, Ms. Mim Seidel and Dr. Donna Wolf received "train the trainer" training from the DPSC in Pittsburgh, PA. Official trainers increase the capacity to expand DPSC services and programs to the AF military community.

April 2009

Following their training, Dr. Wolf and Ms. Seidel conducted a second prevention workshop at Lackland AFB. The GLB workshop flyer was distributed at Lackland, Randolph, Laughlin, Goodfellow and Holloman AFB. The following healthcare providers (11) attended:

SSgt Kenneth Brown	Laughlin AFB (USAF)
Caroline Olson	Goodfellow AFB (Spectrum Contractor)
Paula Naff, RN	Lackland AFB (UPMC/WHMC)
Eva Tenorio	Lackland AFB (UPMC/WHMC)
Rayna Rogiers, RD	Lackland AFB (UPMC/WHMC)
Ellen Kilpatick, RN	Lackland AFB (Government employee)
Lois Wingate, RN,CDE	Lackland AFB (Government employee)
Fahimah Callahan RD, LD	Lackland AFB, (UPMC/WHMC)
Bridget Slattery, RN, FNP,	Lackland AFB (UPMC/WHMC)
Pamela Garwood, RN, FNP-C, BC-ADM	Lackland AFB (UPMC/WHMC)
Athena Martinez	Lackland AFB (UPMC/WHMC)
Tricia Garcia, MPH	Lackland AFB (UPMC/WHMC)
Lt. Col Mark W. True	Lackland AFB (USAF)

Table 2 provides a summary of individuals who have been trained to conduct the GLB prevention program in the AF community.

Table 2. Total Number of Individuals Trained through a GLB Workshop Conducted at a Military Base

	Number Individuals
Lackland AFB Affiliations*	9
Goodfellow AFB Affiliations*	8
Laughlin AFB Affiliations*	1
UPMC Staff at WHMC	15
Wright Patterson AFB Affiliations*	6
TOTAL	**39**

* This includes active duty, government contractors and government employees.

Satisfaction

At the end of the two-day workshop a survey is provided to all attendees to determine satisfaction and if those trained intend to deliver a GLB program. The survey results indicate that those trained were satisfied with the training and prepared to deliver the GLB intervention program.

Research/Feasibility Studies

UPMC staff at WHMC worked with the USAF to recruit and screen participants for the GLB study and the VLM feasibility study. All preventionists are trained according to the DPSC guidelines and prevention materials. Moreover, prevention staff are trained and certified in clinical measurements, which ensures accuracy when taking weight, height, waist circumference and blood pressure measurements.

PARC Services

The PARC website is available for use. The website was expanded to include a resistance training packet by request from the military. Visit the website at http://parcph.org.

Demand for additional DPSC Services

The DPSC team has been in communication with Lt. Col. Mauffray of the Center of Excellence for Medical Multimedia (CEMMS). The following developments are underway:

- GLB program training has been approved as an AF Institute of Technology (AFIT) short course by the AFIT/ENEM. AFIT will cover its members travel expenses to attend GLB trainings, eliminating costs to their military facilities.
- The DPSC in conjunction with CEMMS is hosting a military GLB workshop on January 20-21^{t}, 2010 in Colorado Springs, CO.
- Discussions are underway to expand the DPSC training programs to; Eglin AFB, FL , Travis AFB beyond the hub site of Colorado Springs, CO.

Several USAF staff requested DPSC services, as follows:

- Military leadership from WHMC requested an additional workshop for individuals who were unable to attend the first two workshops. The DPSC will address this request.
- Participants from Goodfellow AFB collaborated with UPMC to conduct a media-based prevention program at their facility in January, 2008

- Wright Patterson AFB received training and requested assistance in organizing a GLB program (calls/ email correspondences are ongoing).
- Andrews AFB has requested GLB workshop training. Their staff planned to attend a GLB workshop in Pittsburgh however they had not engaged the appropriate staff in time to attend. The DPSC staff has been notified, and Andrews AFB staff is exploring the opportunity to attend the January 2010 workshop.

Summary

The DPSC has provided training and services for 39 military representatives. Those in attendance report satisfaction with the program and requests for additional training are being addressed. Plans to provide the training at three additional bases are underway. Plans to extend the official "train the trainer" program to the military are also underway. The PARC, upon request, has added a resistance training packet on the PARC website. DPSC training and PARC expansion is ongoing.

Objective 3. Determine the effectiveness of media-based approach to T2D prevention

Background

The DPSC staff recognizes that opportunities to reach more individuals with T2D and CVD with prevention strategies are needed. Costs and scheduling constraints are often prohibitive, particularly at military facilities. Since scheduling and staffing are frequently reported as barriers to hosting a GLB program, the DPSC developed a media-based approach.

In collaboration with the AF CEMMS, the DPSC staff developed a comprehensive GLB DVD/CD-ROM, outlined as follows:

12-Week Lessons

- Participants are asked to watch GLB DVD/ CDROM one session per week for 12 weeks (takes approximately 60 minutes)
- Lessons focus on healthy eating, physical activity and behavioral modification topics
- Each lesson includes quiz questions and games (learn how to balance consumption of meals and expenditure of energy through physical activity)

Keeping Track

- Participants track their own body weight, fat grams, caloric intake, minutes of physical activity and number of steps (pedometer provided and Calorie King booklets for nutritional information)

Resources

- Supplemental GLB handouts, local and national resources (on CD-ROM)

Communication

- Monthly group sessions are provided by trained GLB lifestyle coaches to discuss prior lessons
- During group sessions, monthly weights are recorded by the lifestyle coaches
- Weekly motivational messages from the lifestyle coaches are sent out via email
- As-needed assistance (can be done via phone or face to face)

Project goals for participants are to:

- Lose 7% of body weight in 12 weeks
- Achieve at least 150 minutes of moderate physical activity per week by the end of the 12 weeks
- Increase daily steps to reach 10,000 steps per day within a 12 week period
- Keep food and activity logs for 12 weeks
- View CD-ROMs and all educational materials/resources in between group classes that are held every 4 weeks

Methods

This was an intervention program designed to test the feasibility of using the GLB CD-ROM in a military community site, therefore no IRB approval was required. Class attendance and monthly weights were collected.

Goodfellow AFB was the military site chosen for the feasibility GLB media-based program intervention. Recruitment began in January 2008. The "Go Team" worked in collaboration with the Health and Wellness Center (HAWC) staff to conduct this prevention program.

Recruitment

Flyers were posted in all squadrons, put in shopping bags at the Base Exchange, Commissary and local General Nutrition Center. The Goodfellow HAWC staff placed advertisements on the medicine group televisions, in the student clinic, as well as the medicine group marquee located outside of the clinic. Furthermore, the team posted an announcement in the base post-master (newsletter) in December, 2008. HAWC staff also made program announcements when attending commander call meetings.

Intervention

All participants were given measuring cups, weight scale, keeping track booklets, pedometers, Calorie King Book, GLB CD-ROM and GLB handouts at the 12-week program. All participants were asked to self-monitor food intake and physical activity throughout the 12-week intervention and were given feedback on their progress. Participants were asked to view the CD-ROM weekly and attend face to face meetings hosted at the base every month. Participants completed surveys at the last face-to-face visit. Participants were asked to answer 10 open-ended questions regarding their satisfaction with the intervention program experience.
Table 3 presents the survey questions.

Table 3: Survey Questions

1) Please tell us what you liked best about the GLB CD-ROM program?
2) Please tell us what you liked least about the CD-ROM program:
3) Did you find the handouts to be useful? Yes_____ No _____
4) Did you watch the CD-ROM? Yes_____ No _____ If No, please describe why not and what we could do to make we this better
5) Did you feel the handouts were organized well and easy to follow? Yes_____ No _____ If No, please describe how we could make this better:
6) Did you experience any difficulty in keeping in touch with the Prevention staff? Yes_____ No _____ If Yes, please describe the difficulty:
7) Was there anything else that you felt should have been included with the CD-ROM program? Yes_____ No _____ If Yes, please describe what should be added:
8) Please list any other suggestions you have for improving the GLB CD-ROM program:
9) Would you be interested in future programs like this at the HAWC? Yes_____ No _____ If Yes, please describe what should be added:
10) Did you reach your 7% weight loss goal? Yes_____ No _____ If No, please describe what could have assisted in reaching your weight loss goal:

Analysis

Analyses were conducted at the individual level. Measures of central tendency (e.g., proportions, means, SDs, medians, etc.) were used for all descriptive analyses. All analyses were conducted using JMP version 9 (SAS Institute, Cary, NC).

Results

There were a total of 76 participants who enrolled in the GLB CD-ROM program at Goodfellow AFB. Sixty-six percent of the participants who enrolled in the program were females. The mean baseline weight was 187 lbs.

Of the 76 participants who started, 13 participants completed all 12-weeks of the program. There was a steady decline in the rates of program attendance during the 12 weeks. Participants who completed the GLB -CD-ROM program on average lost 10lbs. A goal of the GLB-CD-ROM program is to reach a weight loss goal of 7% in 3-months. Participants who completed the full program (n=13) had an average of a 6% weight loss <3 months. The range of weight change ranged from a gain of 2% to a loss of 16.8% in 3-months. As depicted in Table 4, two participants gained weight while 11particpants lost weight.

Table 4. Goodfellow AFB GLB CD-ROM Weight Changes

Patient #	Baseline Weight (lbs)	Follow Up Weight (lbs)	Pounds Lost	Percent Lost (%)
1	250	239	-11	4.5
2	238	219	-19	7.9
3	160	150	-10	6.25
4	215	190	-25	11.7
5	217	209	-8	3.7
6	175	171	-4	2.3
7	222	210	-12	5.4
8	183	176	-7	3.8
9	135	133	-2	1.5
10	126	128	2	Gained (-1.2)
11	159	157	-2	1.3
12	255	260	5	Gained (-2)
13	220	183	-37	16.8
Average	**196.54**	**186.54**	**-10**	**5.92**

Participant Satisfaction

All of the 13 participants who completed the intervention completed a satisfaction survey. Participants reported that they liked the monthly discussions about healthy eating and physical activity and the weekly motivational emails. Several found that" keeping track booklets" to be helpful. All participants reported that the HAWC staff was easy to keep in touch with. One participant stated that they were not able to find a compatible computer for the CD-ROM. Some participants reported that they did not have time or were not interested and therefore did not watch the GLB CD-ROM. Although participants stated they did not meet their weight goal for the study, they did note that they are going to continue using what they learned to hopefully achieve their goal. All of the participants stated that they would be interested in attending more programs.

Summary

These results demonstrate that it is feasible although currently challenging to implement lifestyle interventions at a remote military base. The results show promise with an overall reduction in weight, however, we did not monitor BMI. Recruitment for this project was disappointing. However, albeit a small sample, participants, in general, reported satisfaction with the program processes and are interested in GLB programs at the HAWC.

We recognize that there were delays in recruitment of staff for the "Go Team" and this could have influenced participant recruitment and retention. The most significant limitation of this program was participant follow-up. Only 13 of the 76 who started the program completed it. We suspect that there are several contributing factors to this loss to follow-up. Unlike the face to face GLB, participants did not have the availability of a weekly face to face follow-up in the CR-ROM project. Thus, they may have lost motivation. Competing demands of staff to make follow-up phone calls and appointments, long-distance study oversight, participant deployments (active duty were recruited) and staff turnover could have also impacted follow-up. Future lifestyle programs should include a sufficient number and dedicated staff time to support participant follow-up.
Participant's reported satisfaction with the program and also appreciated HAWC staff accessibility. We suspect that delivering the program as a research study instead of an "easy to access" base program limited engagement.
A thorough assessment for potential program barriers and solutions prior to implementation is critical for future program success.

Objective 4. Determine the effectiveness of primary prevention programs implemented at WHMC (face to face GLB)

Background

We demonstrated the effectiveness of a GLB program with formal classes (face to face) that address good nutrition, safe weight loss methods and the importance of physical activity for people in an underserved, high risk community in Pittsburgh [**10**]. Following DPSC training and with the aforementioned VLM and CD-ROM lifestyle interventions, we hosted a face to face GLB prevention program at WHMC.

Methods

We implemented and evaluated the face to face GLB at WHMC. This study was a non-randomized prospective intervention study that used a single-group design to test the effectiveness of a community-based GLB intervention. This study received IRB approval.

We planned to determine in the military community:

- Demographic characteristics of those who are screened for metabolic syndrome (MetS) and of those with MetS and participate in the GLB program, to examine the relationship with class participation.
- If those with MetS achieve and maintain a physical activity regime for an average of 150 minutes per week of moderate to vigorous exercise and/or lose at least 7% of their body weight in 12 -weeks.
- If those with MetS decrease at least one of their MetS parameters in 12- weeks and maintain it.

Inclusion Criteria

All adults without T2D between the ages of 18-62 years who were either retired or dependents of an active-duty or retired member of the US military. Participants must have been overweight (BMI $\geq$ 25) and exhibited at least three of five parameters for MetS: abdominal obesity (waist circumference > 102 cm in males or >88 cm in females); fasting triglycerides $\geq$ 150 mg/dl; low levels of High Density Lipoprotein (HDL) cholesterol < 40 mg/dl for men and < 50 mg/dl for women; blood pressure $\geq$ 130/85; elevated fasting glucose $\geq$ 100mg/dl < 126 mg/dL. All potential subjects were cleared by a physician.

Exclusion criteria

No pregnant women, subjects with T2D or prisoners were included in the study. Pregnancy was ascertained through self-report. Additionally, subjects currently using glucose lowering medication were excluded as well as subjects on weight loss therapy, those who have had bariatric bypass surgery and those who were unable to provide written informed consent. No active duty members of the US military were included in this study if they were being deployed within 9 months of the start of this study.

There are three phases to this study. Phase I is recruitment/screening; Phase II intervention and Phase III follow-up.

Recruitment

Participants were recruited through healthcare provider referrals, self-referrals, advertisements and flyers. The study population was drawn from the military population residing in San Antonio, Texas. Flyers and advertisements, that listed screening dates and eligibility requirements, are posted at participating AFBs, Army stations, medical centers and through military publications (web-based and print). Primary target sites were: WHMC at Lackland Air Force Base (AFB), the 37th Aerospace Medicine Squadron (AMDS) Health and Wellness Center (HAWC), Kelly AFB, Randolph AFB, Brooks City Base, and Brook Army Medical Center (BAMC).

Healthcare providers from participating clinics were informed about the GLB program so that they could refer their patients during routine medical care. Referral names were then submitted to research staff using IRB approved referral forms.

Screenings

Interested participants who came to a screening appointment were asked to provide informed consent. Clinical measurements taken during screening included WC, height, weight and blood pressure. In addition, participants were asked to complete a demographic and medical history survey.

Research staff reviewed participant lab values required for the study from the first date of lab values available, 12-month period prior to the screening date. Screenings were offered on an ongoing basis therefore eligible participants entered the study at several time points (rolling recruitment). Participants were deemed eligible for the intervention component if screening results show they exhibit at least 3 of 5 parameters for MetS, have a BMI ≥ 25, and met any other aforementioned criteria. Those who did not meet study criteria were referred to programs and support as needed.

Intervention

Participants who met screening criteria and expressed interest in participating in the intervention phase were enrolled in a 3-month GLB program. The GLB program included:

- Twelve weekly classes on nutrition and activity curriculum taught by a dietician and exercise expert
- Opportunities to participate in exercise programs
- Access to health coaches (healthcare professionals) who attend classes with participants, provide peer support and identify barriers and solutions to healthy behaviors

All participants were given measuring cups, weight scale; keep track booklets, pedometers, Calorie King Book, GLB CD-ROM and GLB handouts and were asked to self-monitor food intake and physical activity throughout the 12-week intervention and were given feedback concerning progress. Information was collected every week as well as weights.

Follow-up

Individuals who completed the 3-month GLB program were contacted and invited to return for re-assessment of clinical and laboratory values measurements at least every three months until the end of the study.

Analysis

Sample size estimation/power analysis

We estimated that with 190 people, we would have the ability to detect a statistically significant difference between those who attend at least 80% of the 12 classes in comparison to those who did not attend at least 80% of the 12 classes (80% power, non-directional alpha=0.05) where 60% of those completing at least 80% of the 12 classes would improve at least one risk factor for MetS. We planned on screening 1000 participants in order to enroll 190 participants into the GLB program intervention study. This power analysis was based on a similar research study conducted at the University of Pittsburgh [**10**].

Data Analysis

We used descriptive statistics to examine the demographic characteristics of the study population. Measures of central tendency (percentages, means, or mediums) were used for all descriptive analyses. Comparisons between patients with and without intervention were performed using the χ^2 test or the Fisher exact test for categorical variables. Continuous variables were analyzed using the Student's t test or the Wilcoxon rack sum test. For patients with intervention (n=19), because of a small sample size, the signed rank test was used to determine the difference between before and after intervention at the individual level. The analysis was not "intention to treat." P-values < 0.05 were considered significant. All analyses were conducted using SAS 9.2. (SAS Institute Inc., Cary, North Carolina)

Results

Table 5 summarizes the demographic and clinical characteristics of the total study population. A total of 58 people were screened while 19 were eligible and chose to participate and complete the 12-week intervention. Thirty-nine people were ineligible for this study. There were differences between those who participated and those who were ineligible. Participants who were eligible for the intervention were older, had higher diastolic blood pressure, higher blood glucose, higher HDLc and higher triglycerides.

Table 5. Baseline Characteristics of GLB face to face study

Baseline characteristics (n = 58)					
Variables	Total Screened (n=58)	Ineligible (n=39)	Eligible (n=19)	# of People with Missing Value (Non-Intervention, Intervention)	P value[a]
Age, median (q1, q3), y	53 (42, 59)	50 (37, 56)	58 (54, 60)	0, 0	0.0009
Gender, N (%)					
Men	21 (36.21)	11 (28.21)	10 (52.63)	0, 0	0.07
Women	37 (63.79)	28 (71.79)	9 (47.37)		
Race, N (%)					
White	29 (50.88)	18 (47.37)	11 (57.89)	1, 0	0.73
Black	5 (8.77)	4 (10.53)	1 (5.26)		
Hispanics	21 (36.84)	15 (39.47)	6 (31.58)		
Asian	2 (3.51)	1 (2.63)	1 (5.26)		
Weight, mean (SD), lbs	202.50 (40.73)	199.79 (40.19)	207.93 (42.35)	1, 0	0.48
BMI, median (q1, q3), kg/m^2	31.95 (29.90, 35.80)	31.60 (29.40, 37.00)	32.00 (30.40, 35.00)	0, 0	0.63
Systolic Blood Pressure, mean (SD), mmHg	127.45 (11.36)	125.85 (11.03)	130.74 (11.61)	0, 0	0.12
Diastolic Blood Pressure, mean (SD) , mmHg	78.47 (6.27)	77.05 (5.26)	81.37 (7.27)	0, 0	0.01
Waist, median (q1, q3), cm	103.63 (98.50, 111.00)	102.90 (98.25, 111.00)	108.58 (99.50, 116.58)	1, 0	0.42
Triglycerides, median (q1, q3), mg/dl	104 (69, 162)	86 (67, 128)	141 (91, 169)	8, 0	0.03
Blood Glucose, median (q1, q3), mg/dl	97.5 (90.0, 105.0)	94.0 (88.0, 103.0)	103.0 (97.0, 107.0)	8, 0	0.03
HDLc, median (q1, q3)), mg/dl	51.5 (41.0, 59.0)	54.0 (46.0, 61.0)	43.0 (38.0, 56.0)	8, 0	0.04
Hypertension (blood pressure ≥130/85 mmHg), N (%)	35 (60.34)	17 (43.59)	18 (94.74)	0, 0	0.0002
Abdominal Obesity (≥102 cm in males, ≥88 cm in females), N (%)	50 (87.72)	33 (86.84)	17 (89.47)	1, 0	0.78
Triglycerides ≥150 mg/dl (% yes), N (%)	14 (28.00)	5 (16.13)	9 (47.37)	8, 0	0.02
Glucose ≥100 mg/dl (% yes), N (%)	21 (42.00)	8 (25.81)	13 (68.42)	8, 0	0.003
Abnormal HDLc (<40 mg/dl in males, <50 mg/dl in females), N (%)	19 (38.00)	9 (29.03)	10 (52.63)	8, 0	0.10
# of Parameters, median (q1, q3), N	2 (1, 3)	2 (1, 2)	3 (3, 4)	0, 0	<.0001

[a]For the categorical variables, the P value is generated from the χ^2 test or the fisher exact test. For continuous variables with normal distribution, the P value is generated from the Student's t test. For continuous variables with non-normal distribution, the P value is generated from the Wilcoxon rank sum test.

In Table 6, the results of the 12 week class intervention are presented. Participants lost an average of 11.4 pounds over the 12 week intervention period. BMI decreased by 2 kg/m^2. Both findings were statistically significant. Although not statistically significant, there was a clinically important decrease of 10mmHg in systolic blood pressure. Similarly, glucose decreased by 3mg/dl, but was not statistically significant. There was a significant decline in the number of MetS parameters from an average of three to two parameters.

Table 6. Pre-Post Analysis for the 12 week class Intervention Group

12 week class Intervention Group (n = 19)						
Variables	Pre-GLB	Post-GLB	Difference (=Post-Pre)	# of People with Missing Value (Pre-GLB, Post-GLB)	Paired T Test	Signed Rank Test
Weight, median (q1, q3), cm	198.4 (179.8, 241.2)	193.0 (173.2, 226.0)	-11.4 (-17.0, -2.0)	0, 0	0.0003	0.0004
BMI, median (q1, q3), kg/m^2	32.0 (30.4, 35.0)	30.0 (29.0, 33.0)	-2.0 (-3.0, -1.5)	0, 8	0.0001	0.001
Systolic Blood Pressure, median (q1, q3), mmHg	130 (122, 136)	122 (111, 126)	-10 (-18, 4)	0, 8	0.07	0.07
Diastolic Blood Pressure, median (q1, q3), mmHg	82 (74, 88)	82 (78, 84)	1 (-7, 8)	0, 8	0.88	0.84
Waist, median (q1, q3), cm	108.58 (99.50, 116.58)	105.00 (96.01, 111.00)	-2.83 (-6.50, 1.02)	0, 8	0.13	0.17
Triglycerides, median (q1, q3), mg/dl	141.0 (91.0, 169.0)	147.5 (114.0, 218.0)	-7.0 (-17.0, 29.0)	0, 9	0.49	0.9
Blood Glucose, median (q1, q3), mg/dl	103 (97, 107)	95 (92, 98)	-3 (0, -6)	0, 9	0.07	0.06
HDL, median (q1, q3), mg/dl	43.0 (38.0, 56.0)	42.5 (37.0, 47.0)	0.5 (-4.0, 2.0)	0, 9	0.81	0.82
# of Parameters, median (q1, q3), N	3 (3, 4)	2 (2, 3)	-1 (-1, -1)	0, 8	0.005	0.02

q1=The first quartile; q3=The third quartile; GLB=Group Lifestyle Balance.

Summary

Unfortunately the number of participants in the intervention phase (n=19) of this study did not meet the proposed recruitment number of 190 (power calculation). Therefore, we caution the use of this data for generalizability to the general AF population. There were a number of challenges that we were unprepared for in facilitating this face to face GLB program, as follows:

- Navigating the processes of three levels of IRBs led to a 12 month delay for protocol and consent form approval; this prevention study warranted breaking new ground with IRB and protocol processes.
- Recruitment issues (IRB modifications required to help resolve)
- Advertising opportunities were limited (require zone master's permission)
- Screening process
    - Contacting participants primary care physicians (PCP) was time-consuming and presented additional challenges when attempting to get PCP approvals for participant enrollment
    - Issues with ordering lab working and pulling values on Composite Health Care System (CHCS)
- There were several active duty personnel who wanted to enroll in the program but were unable (obtained an IRB modification to enroll active duty military)
- Screening criteria limited opportunities to include more participants

Due to the low participant numbers (n) only baseline and 3 month (post intervention data) is presented in this report. We will continue to follow the participants who are expected to complete the program in April 2010.

As shown in the screening data (table 5), there were 39 individuals who were ineligible for this study. We recognize that intervention eligibility criteria may be too limiting. Thus, we are continuing to examine the use of BMI and WC in first round community screening events. We also recommend that a thorough assessment be performed prior to a lifestyle intervention study in order to identify challenges (IRB, advertising) to prepare accordingly.

Objective 5. Report on the Cost-Effectiveness of a Primary Prevention Program Implemented at WHMC

Background

People with MetS are at increased risk for developing T2D and CVD as well as at increased risk of total and CVD mortality [**22**]. Improper nutritional practices and physical inactivity are major risk factors of MetS. The GLB program, which combined formal classes addressing good nutrition, safe weight loss methods and the importance of physical activity with individualized support by professionals and a lay health coach, was conducted at WHMC in San Antonio in 2007 to support and sustain participants in their weight loss and physical activity efforts.

The focus of this initiative is the reduction of risk for T2D and/or CVD in the USAF of a military population. In addition, the DPSC of the UPDI developed a modified version of the national Diabetes Prevention Program lifestyle intervention (mDPP) known as GLB and tested its effectiveness in the community and local medical practice settings with patients at increased risk of developing T2D and/or CVD [**23**]. They demonstrated a marked reduction in weight and improvements in components of the MetS in an underserved community immediately following a 12-week GLB intervention. Improvements were sustained at six-month follow-up [**10**].

Therefore, our analysis was to use "real-world" cost and effectiveness data collected from the these interventions to measure whether the GLB intervention program in a military population was cost-effective relative to usual care (or no GLB) in reducing risk for T2D and/or CVD.

Methods

Military-Based GLB Modified from the Original Diabetes Prevention Program (DPP)

The GLB intervention adapted the national DPP [**24**] for use in group-based rather than individualized delivery and decreased the number of lessons from 16 to 12. The 90-minute weekly sessions were offered over 12-14 weeks and were designed to achieve and maintain a 5%-7% weight loss and to progressively raise activity levels to 150 minutes per week of moderately intense physical activity. Retired members of the US military and their adult dependents, as well as adult dependents of active duty US military members, were screened for MetS to determine eligibility of participating in the GLB intervention program. Those who have a BMI of >25 kg/m² and who test positive for three of five MetS risk factors were eligible for the GLB program directed at controlling weight and improving physical activity levels. Risk factors for MetS include [**25**]: Abdominal obesity (waist circumference ≥102 cm in males or ≥88 cm in females); abnormal fasting triglycerides ≥150 mg/dL; low high density lipoprotein (HDL) cholesterol <40 mg/dL for men and <50 mg/dL for women; high blood pressure ≥130/85 mmHg; and elevated fasting glucose ≥100 mg/dL. Participants in the GLB program need to complete 12 weeks of intervention and receive 2 follow-up measurements, including 3 months and 6 months after the GLB program ends (9 months in total). At this point, 19 participants completed baseline and 12-week GLB program; they were included in this analysis.

Development of a Markov Decision Model

Using TreeAge Pro Suite 2009 (TreeAge Software Inc., Williamstown, Massachusetts), we modified our prior Markov decision model [**26**] based on characteristics of the 19 GLB participants to estimate the incremental cost-effectiveness of the military-based GLB program. In the model, we used a base case that examined 57-year-old men and women in monthly cycles over a 3-year time horizon. A 3-year time horizon was chosen to limit projections regarding the continuing effectiveness of the GLB, which is unknown at this point. We defined the incremental cost-effectiveness as the additional cost of using a GLB versus providing usual care, divided by the additional clinical benefit of using the GLB versus providing usual care. For this model, usual care is the absence of a screening program and the intervention program.

In keeping with the reference case recommendations of the Panel on Cost-Effectiveness in Health and Medicine [**17**], we discounted future costs and benefits by 3% annually. We used a modified societal perspective in which the costs of screening, GLB program, diabetes, and complicated diabetes were included, but the costs of patients' time were not

included. To convert all monetary costs to the US dollar rate for the year 2000, we used the US Consumer Price Index. To account for changes in life expectancy and quality of life for diabetes-related health states, we used quality-adjusted life-years (QALYs), which expressed quality as a utility weight ranging between 0 (death) and 1 (perfect health).

Model input parameters are shown in Table 7 below. Clinical outcomes and costs related to T2D and complicated diabetes for both the GLB and usual care were derived from the DPP study [**28**, **29**], the Framingham Heart Study [**20**], the United Kingdom Prospective Diabetes Study (UKPDS) [**21**], and other medical sources/literature [**32**-**39**]. Program costs, recruitment and retention rates, patient demographics, and program effectiveness were derived from the military-based GLB study (i.e., 19 GLB participants) and two community-based effectiveness studies [**23**] that involved risk factor screening and GLB interventions developed by the DPSC of the UPDI to examine mDPP intervention effectiveness in a real-world setting. Program costs were the costs of screening plus the costs of personnel offering the intervention on a per patient basis.

Table 7. Base case values for the decision model and ranges examined in sensitivity analyses

Parameter	Base case value	Range examined (distribution)	Reference
Cohort characteristics			
Starting age, years	57	46–63 (uniform)	WHMC data
Female, %	47.4	7.3-90.3 (beta)	WHMC data
African American, %	5.3	1.4–11.4 (beta)	WHMC data
Angina, %	3.8	1.0–8.3 (beta)	mDPP data (2, 3)
Hypertension, treated, %	84.9	4.5–100.0 (beta)	mDPP data (2, 3)
History of cardiac arrest or MI, %	1.9	0.5–4.2 (beta)	mDPP data (2, 3)
History of stroke, %	1.9	0.5–4.2 (beta)	mDPP data (2, 3)
Peripheral vascular disease, %	4.7	1.3–10.2 (beta)	mDPP data (2, 3)
Probabilities			
Probability of screening risk factor–positive, %	48.3	8.5–87.8 (beta)	WHMC data
Probability of enrollment, %	67.9	7.7–99.8 (beta)	WHMC data
Yearly probability of acquiring diabetes, %			
Not in prevention program, risk factor–positive	10.8	2.9–23.3 (beta)	(8)
Not in prevention program, risk factor–negative	0.4	0.05–0.75 (beta)	(10)
In prevention program	4.8	1.3–10.5 (beta)	(8)
Yearly probability of becoming risk factor–positive, %	4.0	1.0–8.7 (beta)	(9)
Yearly probability of progressing to complicated diabetes, %	7.5	2.0–16.3 (beta)	(8, 11, 13)
Yearly probability of reducing risk factors, %			
Not in prevention program	12.1	3.2–25.9 (beta)	(9)
In prevention program	16.2	4.2–34.4 (beta)	mDPP data (2, 3)
Relative risk of death			
Risk factor–positive	1.7	1.5–1.8 (log-normal)	(14)
Risk factor–negative	1.0	Not varied	Assumption
Stable diabetes	2.0	1.8–2.2 (log-normal)	(15)
Complicated diabetes	2.4	2.2–2.6 (log-normal)	(16)
Utilities			
No diabetes, risk factor–positive, not in prevention program	0.73	0.71–0.75 (uniform)	(8, 17)
No diabetes, risk factor–positive, in prevention program	0.75	0.73–0.77 (uniform)	(8, 17)
No diabetes, risk factor–negative	0.88	0.84–0.92 (uniform)	(18)
Stable diabetes	0.69	0.66–0.72 (uniform)	(8, 17, 19)
Complicated diabetes	0.59	0.51–0.68 (uniform)	(8, 17, 19)
Costs (in US dollars) and multipliers			
Screening, risk factor–positive, $	35	18–53 (uniform)	mDPP data (2, 3)
Screening, risk factor–negative, $	32	16–48 (uniform)	mDPP data (2, 3)
Prevention program, $	219	110–329 (uniform)	mDPP data (2, 3)
Risk factor–positive (yearly), $	1,296	Not varied	(8)
Multiplier for female	1.14	1.05–1.25 (normal)	(8)
Multiplier for African American	0.82	0.70–0.95 (normal)	(8)

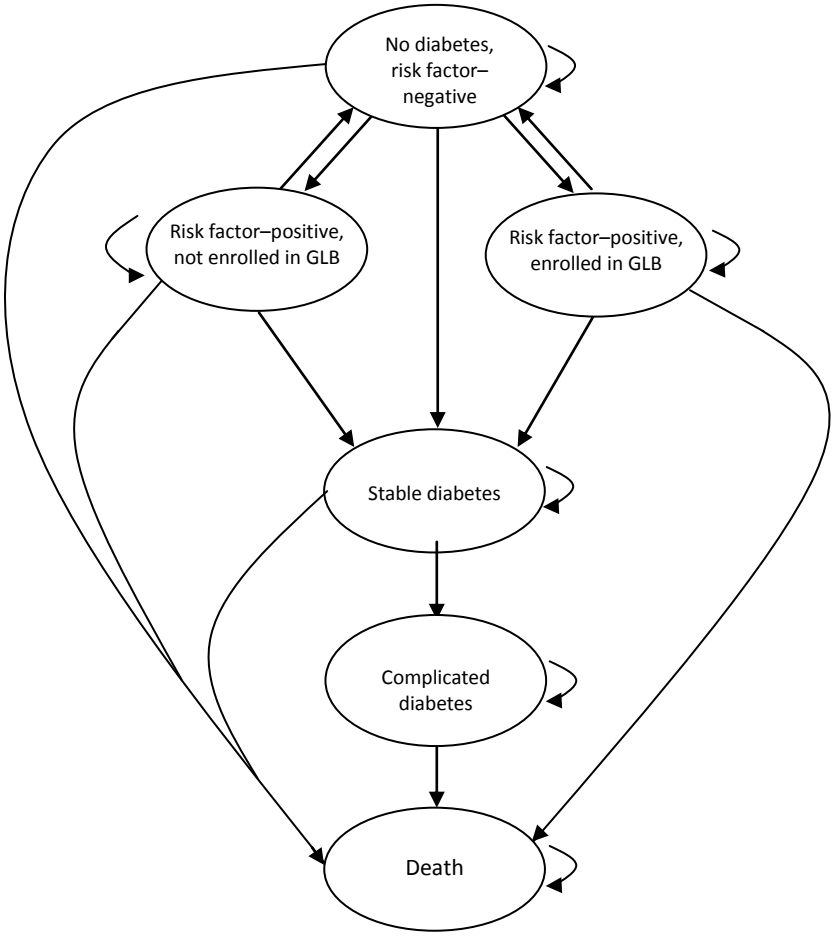
Risk factor–negative (yearly), $	616	Not varied	MEPS
Base diabetes cost (yearly), $	1,684	Not varied	(8)
Multiplier for female	1.25	1.14–1.35 (normal)	(8)
Multiplier for African American	0.82	0.70–0.95 (normal)	(8)
Base complicated diabetes cost (yearly), $	1,684	Not varied	(8)
Multiplier for female	1.25	1.14–1.35 (normal)	(8)
Multiplier for African American	0.82	0.70–0.95 (normal)	(8)
Multiplier for angina	1.73	1.31–2.14 (normal)	(8)
Multiplier for hypertension, treated	1.24	1.10–1.37 (normal)	(8)
Multiplier for history of cardiac arrest or MI	1.90	1.64–2.17 (normal)	(8)
Multiplier for history of stroke	1.30	1.10–1.47 (normal)	(8)
Multiplier for peripheral vascular disease	1.31	1.10–1.53 (normal)	(8)

Abbreviations: WHMC, Wilford Hall Medical Center; mDPP, modified Diabetes Prevention Program; MI, myocardial infarction; MEPS, Medical Expenditure Panel Survey; per person with an expense and good, very good, or excellent perceived health status (http://www.meps.ahrq.gov/mepsweb/).

Basic Model Structure

Figure 1. Basic model structure

Figure 1 below shows a schematic diagram of the Markov model. At the start, subjects without a history of diabetes are evaluated once for risk factors for T2D and CVD. Subjects are considered to be risk factor-positive if they have a BMI of ≥25 kg/m^2 and have three or more components of the MetS. They are considered to be risk factor-negative if they do not meet this set of criteria.



Ovals indicate health states. Subjects may remain within a health state (short curved arrow) or may move to a different health state (straight arrow or long curved arrow) during each model cycle.
In the model, risk factor-positive subjects are eligible for GLB enrollment. Those enrolling in the program show MetS resolution at rates found in the mDPP interventions during the first year of the model. Those who do not enroll show a resolution of MetS at the rate reported for the placebo arm of the national DPP [**29**] during the three years of the model; this same rate of reduction is used for enrolled patients during model years 2 and 3 in the base case analysis. Risk factor-negative subjects are ineligible for enrollment in the GLB, and they develop MetS at the rate reported for the placebo arm of the national DPP [**29**].

Both risk factor-positive and risk factor-negative subjects are at risk for developing diabetes at rates reported by the national DPP. In those who develop T2D, the transition to complicated diabetes is preceded by a stable diabetes stage. Complications from diabetes include neuropathy, nephropathy, stroke, and coronary heart disease. In the model (Figure 1), subjects in all health states can die, and the rates of death are based on age- and gender-specific US mortality rates and the relative risks of death for MetS, stable diabetes, and complicated diabetes [**32**].

Sensitivity Analyses

Best- and worst-case scenario analyses, as well as probabilistic sensitivity analysis were performed on model input parameters. In best- and worst-case analyses, we varied 5 parameters (i.e., Starting age, percentages of female and African American, and probabilities of screening risk factor-positive and enrollment in Table 1) from the military-based GLB study. We did this because these values were the most uncertain due to small sample size (19 GLB participants), and we could perceive the effects of the grouped variation by varying these 5 parameters. In probabilistic sensitivity analysis, the parameters in Table 1 were varied collectively over their listed ranges, with 10,000 recalculations of incremental cost-effectiveness ratios based on random draws from the parameter distributions. Generally, without precise empirical data, sensitivity analyses rely on parameter distributions that reflect uncertainty and the range of likely values. In our analyses, local cost data and utilities were varied over uniform distributions. Incidence and prevalence parameters were varied over beta distributions, relative risks were varied over log-normal distributions, and cost multipliers were varied over normal distributions.

Results

Table 8 below summarizes the results from base case analysis, as well as best- and worst-case scenario analyses. Over the 3-year time horizon of the model, the GLB gained 0.03 QALYs (approximately 11 days in perfect health) at an incremental cost of $40, or $1,725 per QALY gained. These results were due mainly to decreases in incident diabetes with the GLB. Without the GLB, 13.4% of the cohort developed diabetes over 3 years, while with the GLB, 9.1% did. This indicated that the GLB cost $920 per diabetes case averted compared to no GLB. In addition, over this time horizon, little difference between GLB and no GLB was seen (1.6% vs. 1.0%) in complicated diabetes incidence, indicating the GLB cost $7,503 per complicated diabetes case averted compared to no GLB.

In best-case scenario analysis, we found that the GLB compared to no GLB cost $313 per QALY gained, $166 per diabetes case averted, and $1,344 per complicated diabetes case averted. In worst-case scenario analysis, we demonstrated that GLB compared to no GLB cost $70,530 per QALY gained, $37,921 per diabetes case averted, and $311,913 per complicated diabetes case averted.

Table 8. Results from base case analysis, as well as best- and worst-case scenario analyses

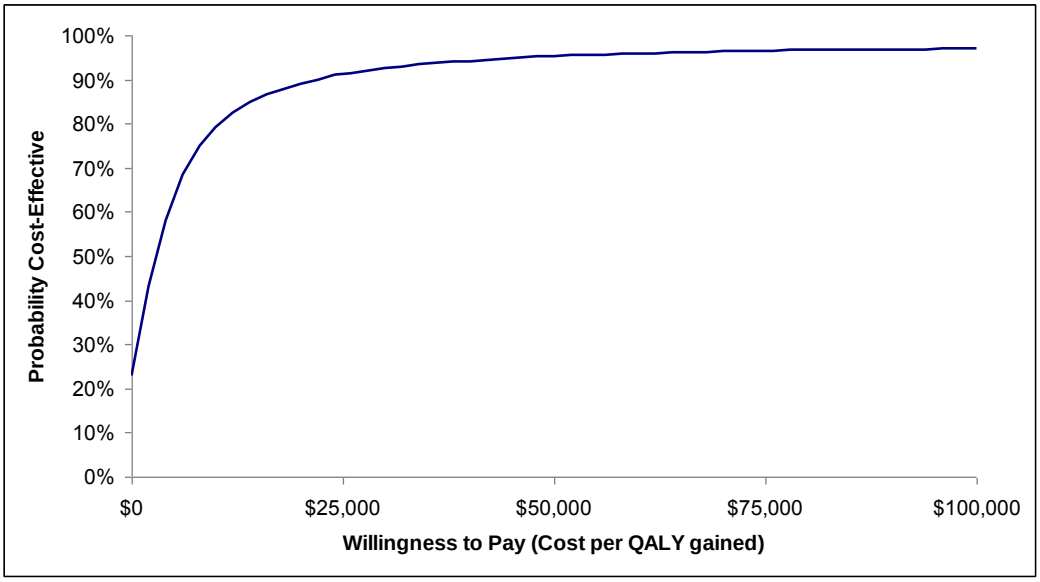
Base case analysis	Strategy	Cost (US$)	Effectiveness	ICER[a]
Cost vs. Quality-adjusted life-expectancy	No GLB	$2,811	2.32 QALY	-
	GLB	$2,851	2.35 QALY	$1,725
Cost vs. Diabetes	No GLB	$2,811	13.42%	-
	GLB	$2,851	9.06%	$920
Cost vs. Complicated diabetes	No GLB	$2,811	1.56%	-
	GLB	$2,851	1.02%	$7,503
Best-case scenario				
Cost vs. Quality-adjusted life-expectancy	No GLB	$3,834	2.20 QALY	-
	GLB	$3,853	2.26 QALY	$313
Cost vs. Diabetes	No GLB	$3,834	22.4%	-
	GLB	$3,853	10.6%	$166
Cost vs. Complicated diabetes	No GLB	$3,834	2.68%	-
	GLB	$3,853	1.22%	$1,344
Worst-case scenario				
Cost vs. Quality-adjusted life-expectancy	No GLB	$1,993	2.4505 QALY	-
	GLB	$2,026	2.4509 QALY	$70,530
Cost vs. Diabetes	No GLB	$1,993	4.58%	-
	GLB	$2,026	4.49%	$37,921
Cost vs. Complicated diabetes	No GLB	$1,993	0.469%	-
	GLB	$2,026	0.459%	$311,913

Abbreviations: GLB, Group Lifestyle Balance; QALY, quality-adjusted life-year. ICER, incremental cost-effectiveness ratio.
[a]ICER indicated cost per QALY gained, cost per diabetes case averted, or cost per complicated diabetes case averted.

The acceptability curve depicts the likelihood of a GLB intervention being favored for a given cost-effectiveness ceiling threshold (willingness to pay). QALY indicated quality-adjusted life-year.

In the probabilistic sensitivity analysis (Figure 2), when all parameters were varied simultaneously over their ranges, using a Willingness-to-Pay (WTP) threshold of $20,000 per QALY gained, the GLB was favored in 89% of model iterations, while using a WTP of $50,000 per QALY gained, the GLB was favored in 95% of model iterations. In addition, the cost-effective probability of 23% at the WTP of $0 per QALY gained indicated the likelihood of being cost-saving for the GLB program.

Figure 2. Probabilistic (second-order Monte Carlo) sensitivity analysis for a GLB Program intervention to reduce the risk for T2D and/or CVD.



Summary

- In the base case and best-case scenario analyses, the GLB program compared to no GLB had quite reasonable expenditures associated with gaining QALYs ($1,725 and $313 per QALY gained) as well as preventing the onset of diabetes ($920 and $166 per diabetes case averted) and complicated diabetes ($7,503 and $1,344 per complicated diabetes case averted). Even, there would be a 23% of likelihood of being cost-saving for the GLB program.
- In the worst-case scenario analysis, the GLB program compared to no GLB still had acceptable expenditures associated with gaining QALYs ($70,530 per QALY gained) and preventing the onset of diabetes ($37,921 per diabetes case averted), although the cost of $311,913 per complicated diabetes case averted was high.
- The GLB delivered in the military-based setting appears to be considered a sound investment.
- Caveats/Limitations:
    - In analyzing the GLB program, we used several conservative practices and assumptions that would be expected to negatively bias our findings. Hence, interpretations of study results are contingent on data quality and model assumptions.
    - As with any modeling exercise, we imposed several simplifications. For example, the probability of acquiring diabetes and progressing to complicated diabetes depends upon a large number of covariates. Moreover, mortality following complicated diabetes depends upon the particular complication each subject develops. The relative risk of death following an amputation, kidney disease, and CVD are quite different, as are utilities for each health state.
    - Although there was no randomized, controlled data, for this analysis the national DPP control arm serves as a reasonable comparison group for the GLB intervention cohort.

CHRONIC CARE MODEL

The Chronic Care Model (CCM), a multifaceted framework for enhancing health care delivery, is widely used in a variety of health care settings to guide system improvement for chronic illness care, including diabetes care [**1**]. Previous studies and our own work have demonstrated the effectiveness of CCM-based interventions on improving the quality of diabetes care [**2**-**5**]. In a meta-analysis of diabetes quality improvement efforts, those that addressed team changes showed more robust improvements in glycemia than any other strategy [**6**].

The CCM, organized around elements that have been shown to improve outcomes, has been used throughout the diabetes project as a framework to guide delivery and evaluation of services. The elements of the CCM include:

1) **Health system** serves as the foundation by providing structure and goals
2) **Community** is used to directly link the hub with community resources
3) **Decision support** serves to assure that providers have access to evidence-based guidelines
4) **Self-management support** helps patients acquire skills and confidence to self-manage
5) **Clinical information systems** provide timely access to data
6) **Delivery system design** is used to restructure medical practices to facilitate team care.

Civilian Populations

It was hypothesized that implementing the CCM in the Pittsburgh Regional Initiative for Diabetes Education (PRIDE) communities (and additional sites) would ultimately result in improved patient clinical outcomes. In addressing all of the elements of the CCM, the investigative team worked on completing the following objectives:

1. Report on effectiveness of CCM at additional named sites
2. Perform cost-effectiveness analyses for the CCM in the community setting
3. Report on effectiveness of telemedicine endocrinologist initiative
4. Report on effectiveness of technology-based education program to extend the reach of the educators beyond the major medical facilities

Objective 1. Report on effectiveness of Chronic Care Model (CCM) at additional named sites

Background

To facilitate a team approach in underserved rural communities, the University of Pittsburgh Diabetes Institute (UPDI) translated the CCM into identified community institutions located in high risk, underserved communities, referred to as the PRIDE sites [**7**]. Each of the following institutions continues to be the hub linking services to additional community sites:

- Conemaugh Valley Memorial Hospital, Johnstown, Cambria County, PA *
- Highlands Hospital, Fayette County, PA*
- Indiana Regional Medical Center (IRMC), Indiana County, PA*
- Uniontown Hospital, Fayette *

*original Pride hub sites

This report provides information on the overall implementation of the CCM with information on program expansion.

Methods

Evaluating the Communities

A two-step approach was used to identify additional sites and determine needs for CCM implementation. The UPDI investigators first facilitated focus group meetings with representatives from each of the PRIDE communities. Using a script outlining the elements of the CCM, a trained qualitative researcher, Martha Terry, PhD, asked questions regarding current interventions and programs being facilitated in the PRIDE sites and gaps in the system. Focus group attendees included people affected by diabetes, physicians, nurses, dietitians and community leaders. Transcripts of all of the focus groups are available. A manuscript that presents the focus group findings has been submitted for publication and is currently under review [**8**]. Through the focus group process, we discovered that in the PRIDE sites:

- There is a shortage of endocrinologists, nurse educators and primary care physicians (nationally and in particular in these sites)

- Sites want "low cost" interventions that could be sustained
- There were fragmented data systems, with most sites still relying on paper charts (Phase 1 we had trained and implemented an approved data system that we later learned provided inaccurate data and frustrated PRIDE users)
- Patients report life priorities such as jobs and insurance; diabetes was considered hopeless and inevitable
- There is a concentration of health services available in Allegheny County, but services were sparse in the PRIDE communities
- Community leaders and providers express need for support of public awareness campaigns
- Centerville Clinics (a network of Federally Qualified Health Center (FQHL) practices) are to be included in the PRIDE initiative and traditional PRIDE sites were to expand their services to local primary care practices

Studies show that those in underserved rural communities are at increased risk for uncontrolled diabetes and hospitalizations. Access to health care, diet, physical activity, and income are also reported to contribute to chronic diseases, which are part of an individual's environment or community. In order to evaluate environmental factors that influence the health of people with diabetes in the PRIDE communities, the second step included geographical environmental evaluation (GEE). A geographical analysis was performed to characterize those with uncontrolled diabetes and their hospitalizations and examine the availability of the local food and health care environment. It was hypothesized that the individuals who reside in counties that are primarily rural would be at a greater risk for uncontrolled diabetes hospitalizations than counties that are more urbanized and that complication risk factors are associated with the presence of different types of food stores and health care locations, controlling for individual and community level factors.

Nine counties in Southwestern PA (Allegheny, Armstrong, Cambria, Fayette, Greene, Indiana, Somerset, Washington, and Westmoreland) were selected from the study area where diabetes centers are located. Age-standardized diabetes hospitalization rates using PA Health Care Cost Containment Council were calculated. Each of the counties was ranked by rurality (the degree of rural area in the county) based on criteria from the US Department of Agriculture Economic Research Service. Statistically significant contributions to the diabetes hospitalization rates by each of the independent covariates (county rank, age, gender) were examined by logistic regression/GEE analysis. GEE regression was used to estimate ratios for having each complication risk factor and their association with the presence of different types of food stores and health care locations, controlling for individual and community level factors.

The analysis included 54,703 patients from nine counties who were hospitalized with an ICD-9 code for diabetes during the 2007 calendar year. Results indicate an association between the rurality of a county and the diabetes hospitalization rates of the county's residents. Residents of more rural counties are 11% more likely to be hospitalized for uncontrolled diabetes compared to those living in areas that are less rural for every increase in rurality ranking.

While supermarkets and grocery stores were associated with a decrease in the likelihood of hypertension, hypercholesterolemia, being overweight and obese, the presence of convenience stores was associated with an increase in the likelihood of individuals having hypertension,

hypercholesterolemia, being overweight, obese, and hyperglycemia, after adjusting for individual and community level factors. A similar trend was found in food service places. The presence of any of the health care locations was associated with a decrease in the likelihood of having these factors. These results indicated that the local food and health care environment at the neighborhood level is a possible ecological determinant of health. There is a clear association between the local food environment and health care locations with risk factors for diabetes complications among individuals with diabetes. A detailed description of the GEE is available upon request. Also, two manuscripts have been submitted for publication [**9**, **10**].

Based on the aforementioned community-identified diabetes needs and geographical analysis of services, programs were determined and established at key locations using the elements of the CCM as a guide.

Health System Organizational Support

UPMC and the UPDI serve as the core for diabetes administration and intervention resources. At the start of the project, there were elements of wariness and distrust of a large academic institution (UPMC) by the community sites. There was a fear of consolidation and acquisition in this era of downsizing and economic challenges. Community practitioners also communicated concerns regarding an academic institution being prescriptive and dictating programs without recognition or appreciation of ongoing community programs and cultural needs. Primary care practitioners (PCPs) have also been reported to be wary of loss of patients to systems with enhanced services [**11**]. Numerous meetings were hosted over time to establish trust. Project plans were developed collaboratively based on need. Administrators at each of the institutions signed subcontracts with UPMC in support of the programs. Routine meetings are held to keep administrators apprised of the project progress.

Community

Focus groups are facilitated in the communities with key community leaders, providers and people affected by diabetes. Questions regarding local, community-based services are presented. Community public awareness campaigns are vetted with UPMC/UPDI and the PRIDE facilities.

Decision Support

The ADA Medical Standards of Care [**12**] and the National Standards for Diabetes Self-Management Education (DSME) [**13**] serve as the mechanism to assure quality and benchmarking for diabetes outcomes. The ultimate goal is to introduce local practitioners to the ADA Standards of Medical Care in anticipation of future efforts that involve the National Commission of Quality Assurance (NCQA) provider recognition program and partnership with the PA Governor's Office of Health Care Reform (GOHR) programs.

Clinical Information Systems

Each institution's data system was evaluated to determine information technology (IT) resources and interoperability needs for an Enterprise Data Management System having an IT platform to serve as a registry and a data management system to facilitate the behavioral and clinical outcomes. Basis for requirements was to assure ease of use, feasible integration and seamless operability by the user(s). The Delphi Data Management System™ (Delphi™) was initially selected to support medical management while the American Association of Diabetes Educators (AADE) Outcome Systems was introduced to

support self-management education processes. These were the first IT systems introduced to the sites that were later replaced with the comprehensive Chronicle data management program.

Delphi™ was introduced into the communities without access to an electronic medical record (EMR). Delphi™ was highly recommended by colleagues including the Medical Director of ADA. At the time, IT diabetes systems were just being developed and limited reports of their success were available at the time. PRIDE site staff were trained and Delphi™ was integrated into selected practice sites.

Systems that help to define, measure and collect relevant data on education outcomes, that specifically include elements of behavior change were not available. Educators in the AADE (of which both UPMC and military educators are members) determined that comprehensive efforts in defining, measuring, collecting, and reporting of diabetes education outcomes for advancing the practice of DSME were needed. Both external environmental influences and organizational efforts converged in guiding the activities that resulted in the AADE Outcomes Project. A description of the project activities, the components developed and their application to diabetes education practice are described in AADE/UPMC publications [**14**-**17**].

Self-Management Support

The National Standards for DSME [**13**] administered through the ADA recognition program provides the framework for quality education and reimbursement for services [**18**]. Medicare and other third-party payers were reimbursed for programs when they meet ADA requirements. Reimbursement is linked to codes, and charges are typically based on Medicare rates [**19**]. In a fiscal environment where health care administrators are skeptical of services that do not generate revenue, tracking reimbursement in justifying positions is critically important. Reimbursement is critical in generating revenue to support nurse and dietician educators who provide DSME and those who direct the nurse-directed clinics. Educators can be the target of cost-cutting initiatives when financial stability cannot be demonstrated. Medicare (requires that in order to bill for DSME, programs must meet the National Standards for DSME and be approved through the ADA Recognition Program. Education charges are based on Health Care Common Procedure Coding System (HCPCS) “G” codes.

The UPDI employs a diabetes educator who provides DSME in UPMC Community Medicine, Inc. (CMI), PCP offices (located in PRIDE practices) and two traveling educators who provide DSME in the network of Centerville FQHC clinics and PCP offices. The UPDI serves as a hub resource for the educators and PRIDE programs to effectively establish a DSME program. Educators are instructed on their responsibility in collecting the following data:

- number of patients receiving DSME
- changes in self-care behaviors
- changes in clinical outcomes
- collecting data for ADA education recognition
- reimbursement data

To gain and maintain ADA recognition status, an established system (committee, governing board, advisory body) involving professional staff and other stakeholders participates annually to review the program according to the National Standards. UPDI worked with education staff at all of the PRIDE sites who met regularly, collected necessary data, met specific criteria and applied for ADA DSME PRIDE Program Recognition in order to assure quality education and to set the stage for exploration of

reimbursement for DSME services. Every diabetes patient receiving care in the PRIDE community is offered and has access to DSME and Medical Nutrition Therapy (MNT) Services. All of the educators were instructed to collect and report reimbursement data from their respective programs.

Delivery System Design

Effective chronic illness management also requires attention to delivery system design [**1]**. Team-based care has repeatedly been shown to improve outcomes [**6**], yet it is often unavailable in underserved communities and in primary care practice settings. Based on the feedback collected in the focus groups, nurse supported clinics were established in 4 of the 5 PRIDE sites (Conemaugh Diabetes Institute, Highlands, IRMC and Uniontown Hospital). The staff from each of these hub facilities was required (UPMC/PRIDE subcontracts) to investigate their respective communities to provide additional outreach services from their hub site. A "traveling" diabetes education team was employed by UPDI and deployed to the practices within the Centerville FQHC Clinics.

Results

Additional sites

Additional sites were identified by the staff from the UPDI and PRIDE sites based on focus group and GEE findings. They are as follows:

Centerville Clinics, FQHC (additional program)

- 10 primary care offices:
  - Fayette County: Uniontown, Connellsville, Fairchance, Republic
  - Washington County: Centerville Clinic (main) Bentleyville, California, Washington and Charleroi
  - Greene County: Carmichael
  - Cornerstone Clinic (need identified 9-09 services to begin 10-09)

*Conemaugh Valley Memorial Hospital, Johnstown, Cambria County, PA **

- 3 Community primary care offices:
  - Dr. William Pruchnic Johnstown, PA
  - Dr Jagdish Patel Johnstown, PA
  - Dr Molly Trostle Ebensburg, PA
- Meyersdale Community Hospital, Meyersdale, Pa.
- Miners Medical Center, Hastings, Pa.

*Highlands Hospital, Fayette County, PA**

- 5 community primary care offices:
  - Dr Paul Means/Dr Tiffany Pluto Scottsdale, PA
  - Dr Rachel Esposito Mt Pleasant, PA
  - Dr William Kozak, Family Practice Connellsville, PA
  - Dr Gina Canada, Connellsville, PA
  - Dr Albert Enany, Connelsville, PA

*Indiana Regional Medical Center (IRMC), Indiana County, PA**

- Primary Care Network Clarksburg, PA

*Uniontown Hospital, Fayette **

- 3 community primary care offices:
  - Mountain Springs Medical Associates Farmington, PA
  - The Doctors Office/ Dr Linda Burstynowicz Brownsville, PA
  - The Doctors Office-Masontown/Dr Brian Mudry Masontown, PA

*original PRIDE hub sites

Elements of the Chronic Care Model

Health System Organizational Support

Administrators from all of the health systems continue to be collaborative. Routine meetings are facilitated with PRIDE site representatives and administrators. UPDI is spearheading efforts with the PA Department of Health and its PA Diabetes Action Plan and the Governor's GOHR, to explore opportunities for the provision of quality diabetes care and long-term sustainability. Partnership between academic, large health system and outlying community institutions and practices was convened at a diabetes planning meeting with national diabetes experts in attendance.

Community (Additional community partnerships)

UPMC/UPDI facilitated public awareness campaigns and programs that were done in southwestern PA.

The UPDI established collaborations and organized links with PRIDE sites and other ongoing federally funded community programs. "Steps to a Healthier Pennsylvania" is described as an innovative national model to reduce the cost and health complications of chronic diseases. While PRIDE built sustainable care clinics and practices, the Steps program gave communities the tools to help residents adopt healthy lifestyle behaviors that reduce the risk factors related to poor nutrition and physical inactivity. Administered by Area Health Education Centers (AHECs) & funded by the PA Department of Health through a grant from the Center for Disease Control and Prevention (CDC), Steps worked with UPDI, PRIDE, community groups, health care providers, schools and worksites in several PA counties including Fayette. The Steps team refers to the influence of their community based efforts and collaborations on reduction of hospitalizations in the PA counties where Steps was hosted. The "Steps Diabetes Hospitalization Data Report Bureau of Health Promotion and Risk Reduction July 2008" report includes diabetes-related hospitalization data collected by the Pennsylvania Health Care Cost Containment Council. Although this work was not led or funded by the UPDI/PRIDE staff, Steps leadership acknowledges the added benefits of the community collaboration with this DOD government supported diabetes project.

Decision Support

All PRIDE hub sites are using the ADA Standards for Medical Care [**12**] and the National DSME Standards [**13]** for benchmarking and program processes. Figures 2-15 below demonstrate tracking of ADA target HbA1c goal. Unfortunately, challenges with HIPPA requirements limited review of paper records, thus we could not collect all of the relevant practice data. Based on communications with PRIDE site staff, problems with practice clinical inertia continue and are attributed to limited resources. Practice staff report being overwhelmed with clinical responsibilities.

Clinical Information Systems

Practitioners and staff reported many challenges in implementing the Delphi™ system. They cited numerous errors in data that was being tracked (e.g. an 80 year old woman with diabetes recorded as pregnant), the system was not user-friendly and required precious staff time in entering patient information. In response, UPMC organized an audit of the system.

Based on community feedback and the results of the audit, UPMC requested that Delphi™ be replaced by another IT data management system. Subsequent to the request, per recommendations from AF/SGR, IT vendors were invited to submit proposals and demonstrations of various IT systems (Healthy States, All Scripts, Flipside) which were presented to representatives from UPMC, UPDI, SGR and PRIDE. Based on capabilities, cost, ease of use and service, Flipside and the Chronicle system was selected.

The AADE Outcomes Systems (formerly referred to as National Diabetes Outcome System) was used to collect and monitor DSME data by UPMC and PRIDE sites as part of a demonstration evaluation process in a prior funding cycle. As has been reported in a series of communications, there have been challenges in executing an agreement with the AADE. The content development for the AADE Outcome System was under an agreement between the AADE and UPMC prior to the DOD award. After the content was developed, in our previous efforts the AADE System was evaluated and validated by UPMC and reported. National publications and presentations summarize the findings of the evaluation and have been previously submitted [**14**-**17**].

During the evaluation process in UPMC and PRIDE communities, UPMC determined that the AADE System was cumbersome, necessitated that the patient spend an extensive amount of time completing the tool (minimum 20 minutes) and required the addition of clinical, medication management, patient snapshot, patient-provider interface and new letter manager tools [**16**]. The findings of the process evaluation and the challenges for users of the tool were communicated to AADE. AADE leadership and UPMC agreed that without the additions, the System was not robust and would not be useful in helping the diabetes educator in capturing necessary and relevant data. AADE agreed that they would shorten the tool (based on the process evaluation) on a separate agreement. In recognition that these components were critically important to the development of any diabetes education system tool, UPMC developed these systems (clinical, medication management, patient snapshot, patient-provider interface and new letter manager tools) for use by educators serving both civilian and military populations.

In discussions (and through demonstrations) with the PRIDE and WHMC teams, it was agreed that the numerous challenges and delays in using the AADE System were unacceptable. There is a critical need for an education system tool and relying on the final development and release of the AADE System was affecting workflow and completion of important efforts on the project.

Subsequently, outlined in an agreement between UPMC and AADE, it was determined that AADE would retain rights to the intellectual property that had been developed and would use their system for free access to its members and potential sale to non-members. In the agreement reached on Jan. 2008, AADE agreed to a license for AF WHMC and PRIDE users. The plans with AADE were discussed and reported to AF SGR.
It was determined that the Chronicle System would incorporate DSME questions based on UPMC, PRIDE and AF educator feedback. The system is built on requirements for ADA DSME recognition and was

presented to the ADA. The Chronicle diabetes clinical management system is being implemented in PRIDE sites that do not currently have a diabetes management tool and/or EMR. The Chronicle DSME component is being tested in all of the PRIDE nurse-directed clinic sites. Thus, it was agreed that a system that included the already developed clinical management, medication, assessment, goal setting, and educator documentation be expanded and developed into a user-friendly comprehensive system. The UPMC team continues to evaluate the education tool with input from PRIDE educators. In collaboration with the ADA, an education recognition program (ERP) has been created. Plans for deployment to >2,000 ERP ADA programs are being reviewed.

Self-Management Support

DSME and support is on-going. All sites have been awarded ADA DSME recognition. Current certificates reflect ongoing recognition award.

The Conemaugh Diabetes Institute received recognition prior to the formation of the PRIDE initiative and has maintained ADA recognition. The additional partner sites at Conemaugh received recognition as follows:
Meyersdale Medical Center expansion site received ADA recognition on June 23, 2008.
Miners Medical Center expansion site received ADA recognition on June 23, 2008.

The Highlands Hospital was awarded ADA recognition on August 27, 2008. Received ADA recognition on August 8, 2008 and began billing for DSME services in January 2009. They report receiving regular reimbursements.

The IRMC received recognition prior to the formation of the PRIDE initiative and has maintained ADA recognition.

Uniontown was awarded ADA recognition on January 15, 2008.
The Uniontown additional site, Mountain Springs Medical Associates, was awarded ADA recognition on August 19, 2008 as an expansion site.

Centerville Clinics

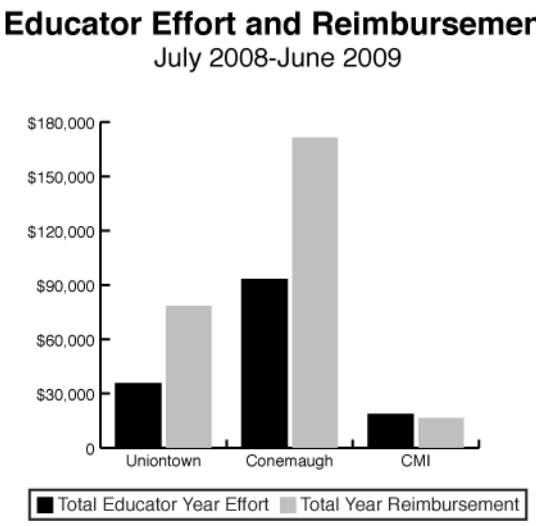
A traveling diabetes educator provides DSME at Centerville Clinics (FQHC). (Centerville Clinics received ADA recognition on August 14, 2008.) Centerville Clinic administration was reluctant to institute billing for their patients as they use a sliding scale and thought that it might deter patients from coming into the site for education. We have met with them several times to discuss sustaining their program. They have agreed to institute billing for services before the end of 2009.

Delivery System Design

Nurse–directed clinics were established at Conemaugh, Highlands, Indiana and Uniontown Hospitals. The nurse educators expanded service to their hospital affiliated primary care practices and clinics. Three traveling diabetes educators are employed by the UPDI and provide DSME and MNT services in 7 Community Medicine (CMI) and PRIDE FQHC offices.
Sustainability

Only Uniontown, Conemaugh, and CMI educators were able to collect and report accurate reimbursement data. Education effort can be supported in these settings. As shown in Figure 1, reimbursement exceeds education effort at Conemaugh Diabetes Institute and Uniontown Hospital. The CMI educator currently has education visits and classes at 7 PRIDE primary care sites. Reimbursement and education effort is comparable at the CMI program.

Figure 1.



Clinical Outcomes (Demonstration of Implementation of CCM at additional named sites)

The graphs included in this report demonstrate reduction in HbA1c values and associated estimated health care savings for patients who received care associated with the nurse-directed clinics. The PRIDE site data represents aggregated data from the original PRIDE site plus the additional sites of expansion with their updated findings.

The graphs represent the effects of the programs that were specifically implemented to reduce this value. The time frames represent the time in which we could capture "clean" data. Other values, for example, blood pressure, etc. have been measured, but not consistently and easily captured with fragmented data systems and paper charts. The health care dollars savings were calculated based on the reduction of the HbA1c level referred to in a Wagner publication [**20**].

Figures 2-11 represent reductions in patient HbA1c levels at each of the PRIDE program sites. These figures illustrate data that was captured and analyzed to contribute to the interim report delivered June 15, 2009.

Uniontown Hospital (Data represent Uniontown and PCP sites)

A diabetes nurse-directed clinic was established at Uniontown Hospital. At the inception of the program, Uniontown had employed an endocrinologist. Due to a number of circumstances, the endocrinologist no longer provides care at the clinic. Currently, the nurse provides service within the clinic and travels to local primary care practices to provide service in helping patients with medication adherence, nutrition counseling, promoting activity, monitoring, etc.

Figure 2.

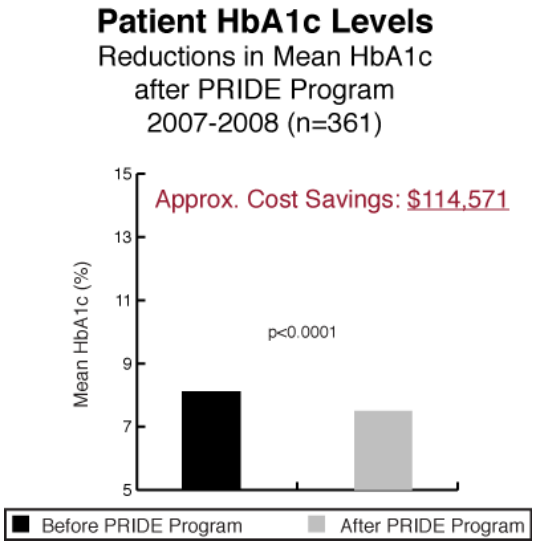
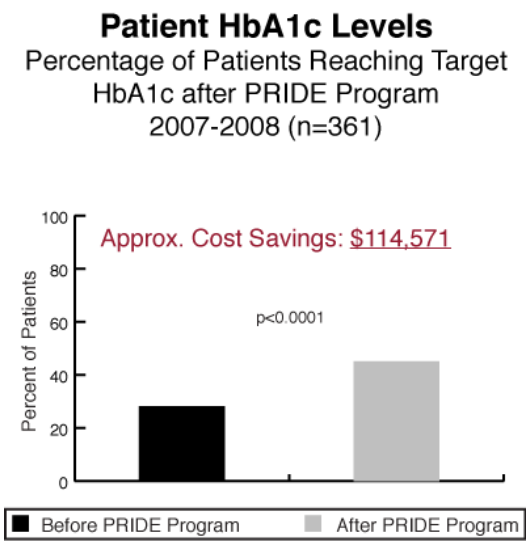


Figure 3.



There was a significant reduction in HbA1c in the Uniontown clinic population with an estimated cost savings of $114,571. The program was able to effectively increase the number of patients who met ADA goal of <7%. This effect was maintained over time.

Centerville Clinics (Data represents all Centerville sites)

Centerville Clinics provide care for those insured through the United Mine Workers. The clinics are part of a FQHC. Prior to the PRIDE program, the physicians in the clinic did not have access to a nurse or dietitian for their patients. The UPDI employs a traveling nurse and dietitian from the community who travel to all Centerville Clinics. A nurse and dietitian rotate to the Centerville primary care clinics and practices to provide service in helping patients with medication adherence, nutrition counseling, promoting activity, monitoring, etc. They have provided service for >800 patients, however, data is captured by paper chart review and is ongoing.

Figure 4.

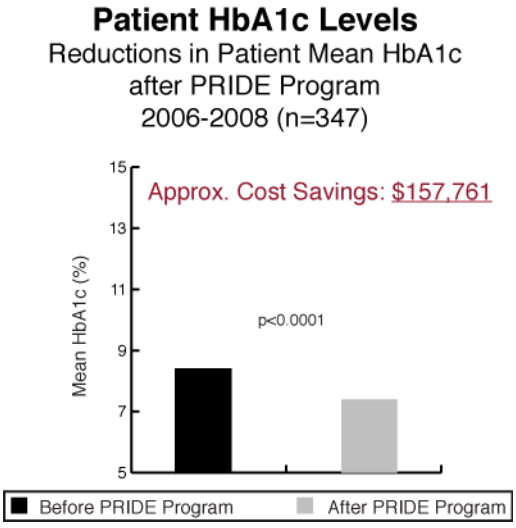
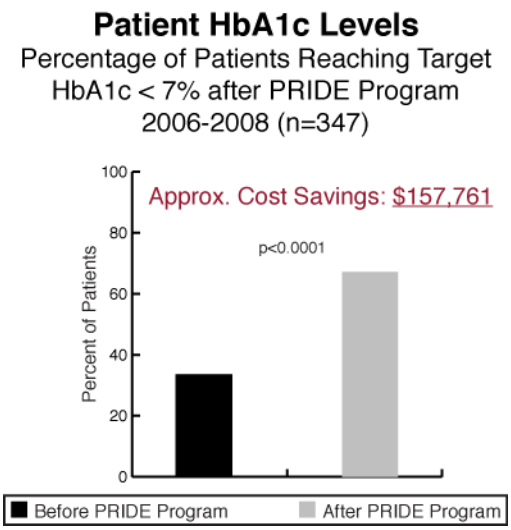


Figure 5.



There has been a 1% reduction in HbA1c levels in patients being cared for in the Centerville Clinics and a significant increase in the numbers of patients reaching ADA target goals <7%. There was an estimated cost savings of $157, 761.

Highlands Hospital (Highlands and Primary Care sites)

The Highlands Hospital PRIDE Diabetes Clinic is another nurse-directed clinic, where patients are seen for medication adherence, blood glucose monitoring, foot exams, nutrition and exercise counseling. The Highlands' nurse also provides support for the local PCPs. Available data for the Highlands program also demonstrates the effectiveness of a nurse-directed support clinic.

Figure 6.

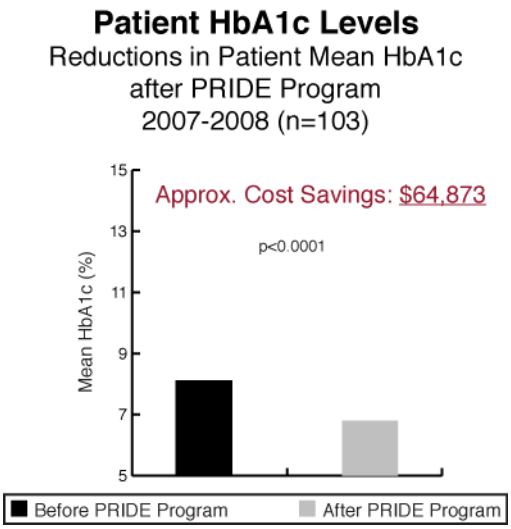
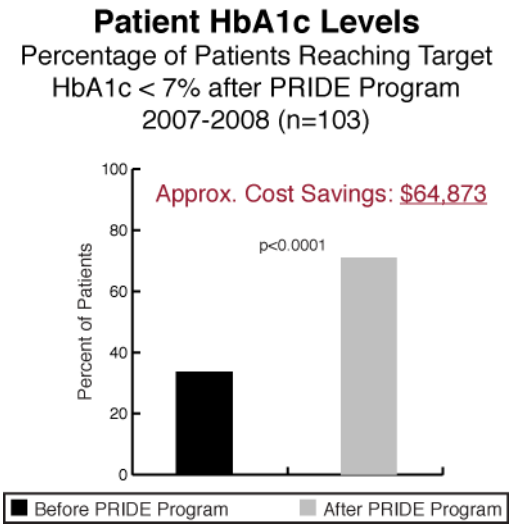


Figure 7.



There was a significant reduction in HbA1c levels in this population with an estimated cost savings of $64,873. The team at Highlands Hospital has been very effective in increasing the numbers of diabetes patients reaching target goals from 33 to 71% while maintaining this improvement over time.

Indiana Regional Medical Center (IRMC)

IRMC facilitated a similar program. They received recognition from the ADA and are able to reimburse for services. The results of their diabetes program are represented below in Figures 8 and 9.

Figure 8.

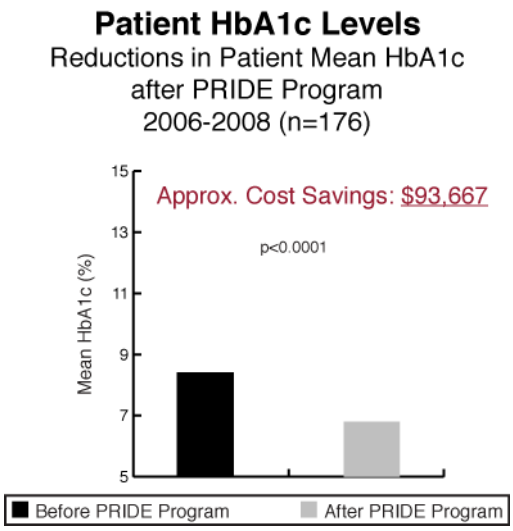
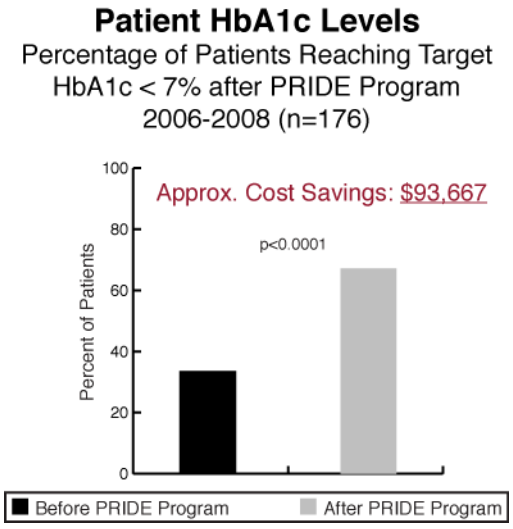


Figure 9.



There was a significant reduction in HbA1c levels and an estimated cost savings of $93,667.

Conemaugh Diabetes Institute (Conemaugh Institute and outreach sites)

Patients in the Johnstown and the surrounding area receive diabetes services at the Conemaugh Diabetes Institute. At the program inception, an endocrinologist provided diabetes services within the clinic however he has since retired. The nurse-directed program currently provides prevention and support services for diabetes adult patients and hosts a pediatric clinic for Children's Hospital once a month. The nurse has also begun to provide "traveling" service to the additional Conemaugh sites, Myersdale and Miners facilities. Figures 9 and 10 represent improvements in HbA1c levels data on patients receiving service at the clinics.

Figure 10.

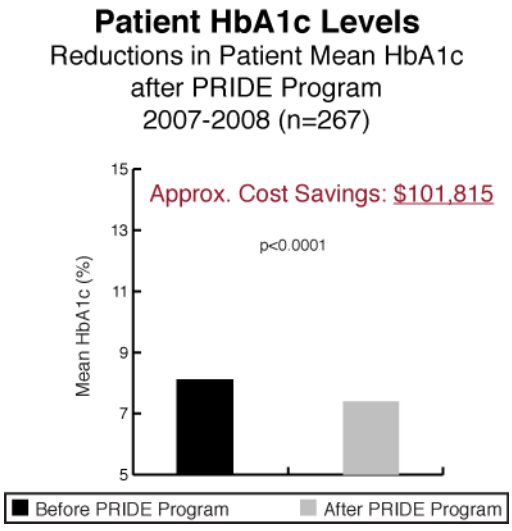
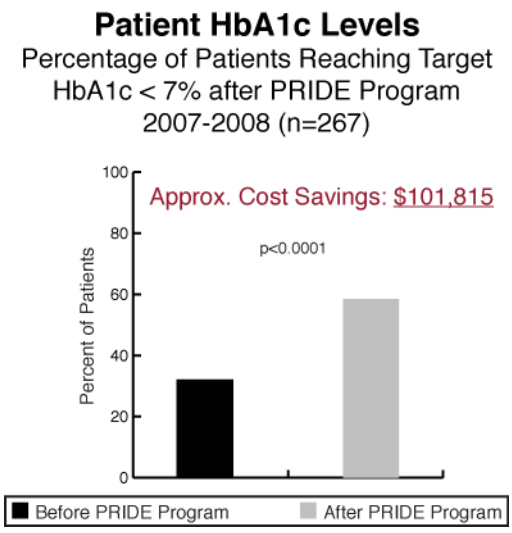


Figure 11.



There was a significant reduction in HbA1c levels and an estimated cost savings of $101, 815.

Clinical and Cost Outcomes

The ADA treatment goal is to keep HbA1c levels <7%. For every 1% reduction, there is a reduction in cardiovascular, kidney, nerve and eye disease and health care dollars with every percent decrease as follows:

HbA1c ranges and associated reduction in health care dollars:

10 – 9%	$1205
9 – 8%:	$869
8 –7%:	$601
< 6%	$378

The graphs below represent the time in which accurate data could be collected and illustrate reduction in HbA1c values with associated approximate health care savings at all of the PRIDE sites. These 1,385 patient values were presented in an interim report submitted to AF/SGR June 15, 2009. These findings indicate that a low cost nurse clinic as part of the CCM has made significant strides in lowering HbA1c levels that have the potential to save significant health care dollars. As depicted in the figures below, the PRIDE sites were able to save over $500,000 health care dollars while increasing the number of people who are at ADA target goals. The consistent percent improvement in risk reduction illustrated suggests that the programs have great potential to continue to improve glycemia and to increase health savings over time.

Figure 12.

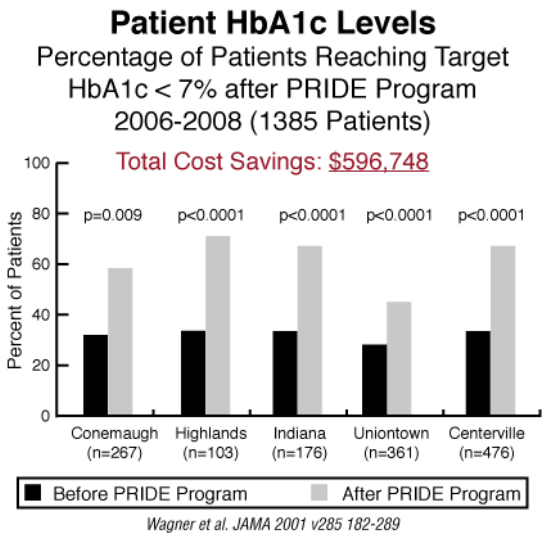
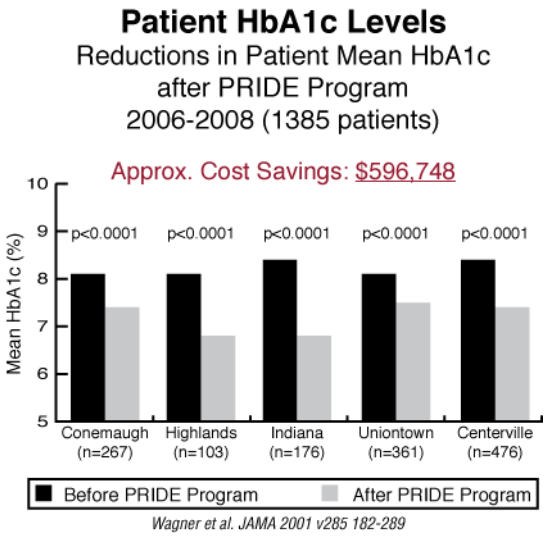


Figure 13.



Since that time we have included 290 more patients with the additional sites. Figure 14 and 15 illustrate improvements.

Figure 14.

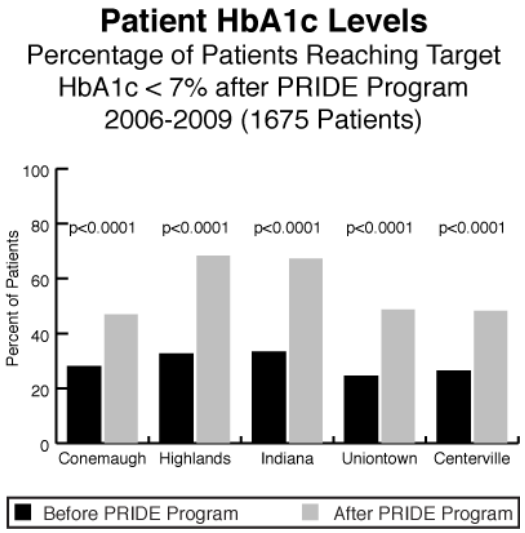
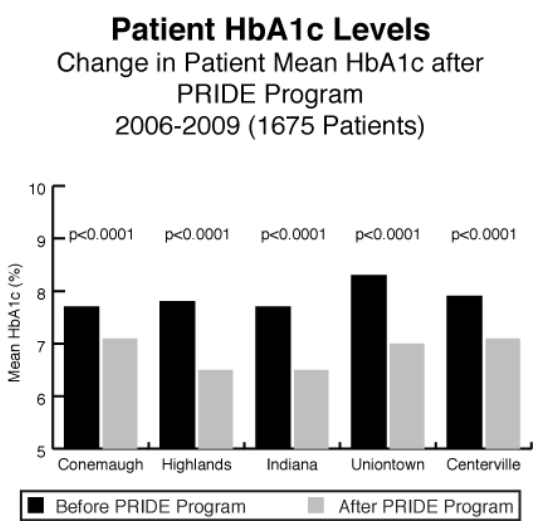


Figure 15.



We have also been able to capture LDL levels with the introduction of the Chronicle system. Figure 16 represents significant improvements in LDL levels. Through patient chart review we captured body weight for 543 patients. Figure 17 represents significant improvements in patient body weight.

Figure 16.

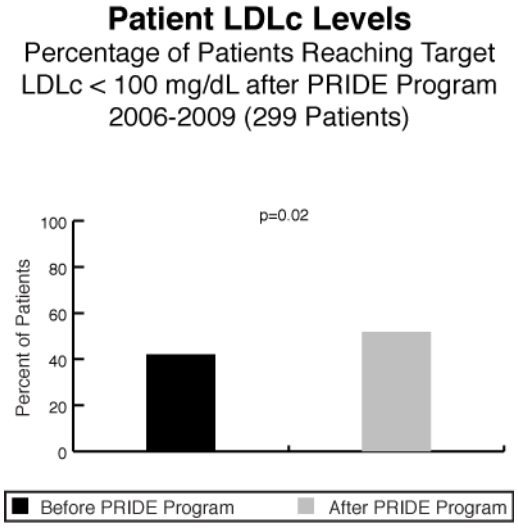
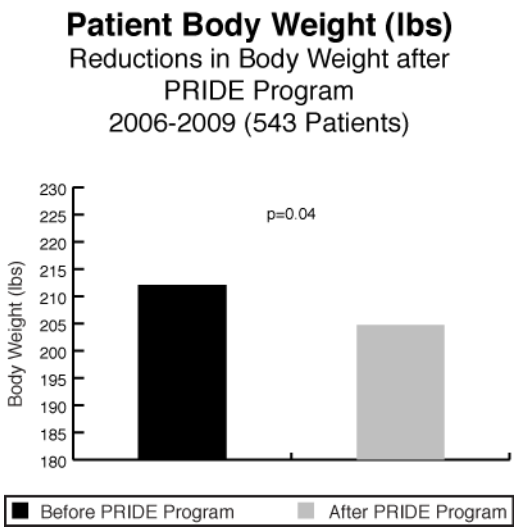


Figure 17.



Summary

In this report, we demonstrate that by attending to the key elements of the CCM (organizational support, community resources, decision support, clinical information systems, self-management support, and delivery system design) we were able to support rural clinics and their associated additional sites and ultimately improve patient diabetes outcomes.

We learned that a critical first step is to carefully assess and engage the **community**. During focus group meetings and geo-environmental analysis, we identified environmental and health care needs that are associated with improved health and quality chronic disease management. By identifying community-specific needs and engaging local stakeholders early in the process, we were able to collaborate on project plans with their full support. This is extremely important as these stakeholders will be required to sustain the project outcomes for the future. The community assessment also opened avenues for partnerships with other federally funded programs (Steps) and helped to avoid duplication of efforts.

Decision support was based on the ADA Medical Standards of Care. We planned to collect, at a minimum the ABCs of diabetes (HbA1c/Blood pressure/LDL Cholesterol), on all of the patients receiving care through the PRIDE clinics. However due to numerous **clinical information system** challenges and disparate systems (that have been reported and subsequently resolved), we relied on those patient HbA1c and LDL levels in which we could capture "clean" data as a measure for improved patient diabetes outcomes. Both HbA1c and LDL levels improved significantly in patients receiving care in all of the PRIDE programs. We do recognize that other process improvements may have influenced the outcomes.

For every 1% reduction in HbA1c value, there is a significant reduction in cardiovascular, kidney, nerve and eye disease. The ADA treatment goal is to keep HbA1c levels <7%. Cost savings (health care dollars) for every percentage HbA1c reduction have been reported. We applied this formula to our site values and are able to demonstrate an estimate of health care savings. We anticipate an ongoing cost savings for these programs if the HbA1c levels continue to improve through these processes.

We believe that much of the program success is a result of attention to **system re-design**. With the availability of team-based care and **self-management** education services provided through the nurse-directed clinics and the traveling educators, we were able to assure quality. In tracking reimbursement for services, we are also able to demonstrate opportunities to sustain the nurse positions.

The PRIDE network is currently involved in the PA Commission for Chronic Disease. Through the Governor's program, the CCM is being rolled out in "learning collaborative" programs across PA. The program facilitates incentive payment by PA insurers to primary care practitioners to improve diabetes quality care and support self-management services. The PRIDE collaborative began in July 2009. The sites and practices are trained on the use of a consistent data system, so that all diabetes outcomes can be consistently captured and reported. The PRIDE program is already in a position with a developed infrastructure to actively engage in the state program. This initiative affords the opportunity for diabetes programs to be rewarded for quality services and sustained for the future health of the constituents.

We conclude that the CCM is a useful framework to improve diabetes outcomes in a rural, underserved community. Through team-based care supported by nurse-directed clinics and traveling diabetes

educators, we had a significant impact on clinical outcomes. We also were able to demonstrate that these programs could be sustained through reimbursement for services. These findings have great potential for informing policy makers, like the PA Governor's Chronic Care Commission, in demonstrating powerful programs at low expense.
The limitations of our project are recognized and are as follows:

- Extended period to build and maintain community trust
- Disparate information technology systems
- Numerous challenges with Delphi™ and AADE Outcome System and them gaining acceptance in selection of data management system tools
- Extended time needed to educate and convince the community about diabetes, its risk factors, and need for service
- Educating practitioners and patients on necessary and available services, like DSME, available in their community
- Time needed in working toward policy change with reimbursement
- Lack of control over practicing physicians – outside of UPMC network
- Physician clinical inertia first needed to be overcome
- Inability to control for outside influences on program outcomes
- Inability due to HIPPA requirements and honest-broker to do chart review in clinics
- Billing at FQHC

Although this study was performed with a large health system and in rural communities, it serves as a model for others to explore creative solutions. Innovative technological methods, integrated data management and data bases, virtual teams and community-based education afford other exciting opportunities that need to be explored.

Objective 2. Perform cost-effectiveness analyses for the CCM in the community setting

Background

Diabetes is a serious, costly and increasingly prevalent cause of morbidity and mortality, resulting in major clinical and public health problems in the US [**21**, **22**]. Quality diabetes care is acknowledged to be essential to prevent acute complications and to reduce the risk of long-term complications [**23**], and various technologies (including glucose-lowering drugs and other relevant medications as well as evidence-based treatment guidelines) [**12**, **13**] that reduce diabetes burden are available. However, diabetes care outcomes such as glycated hemoglobin (HbA1c), blood pressure levels, and LDL cholesterol levels often fall below recommended standards, regardless of health care setting or patient population, emphasizing the necessity for system change [**24**].

Previous studies have demonstrated the effectiveness of CCM-based interventions on improving the quality of diabetes care [**1**, **2**]. Only three [**3**, **25**, **26**] of these studies are published randomized controlled trials (RCTs) and apply all six elements of the CCM intervention for diabetes care, but the evidence from these studies is consistent with the notion that implementing a CCM-based intervention improves the quality of diabetes care. Although multifaceted interventions based on the entire elements of the CCM improve outcomes of people with diabetes [**1**,**2**], little is known about the cost-effectiveness of this type of approach.

Methods

We used a computational simulation modeling of a 3-year clinical outcomes and costs of intervening with a CCM, provider education (PROV), or usual care (UC) intervention strategy for people with diabetes in an underserved community.

Results

Our study reveals that the application of a multifaceted diabetes care intervention using the CCM in the community primary care practice setting would be a sound, cost-saving investment compared to the PROV (provider continuing medical education) intervention strategy. In addition, implementing the CCM intervention strategy in an underserved community was potentially cost-effective compared to the UC intervention strategy. A manuscript has been submitted for publication and is currently under review [**27**].

Summary

Evidence on the cost-effectiveness of the CCM is just beginning to emerge, and this is the first study to determine the cost-effectiveness of implementing entire elements of the CCM in an underserved community based on the RCT data. This study reveals that the application of a multifaceted diabetes care intervention using the CCM in the community primary care practice setting would be a sound, cost-saving investment compared to the PROV intervention strategy. In addition, implementing the CCM intervention strategy in an underserved community was potentially cost-effective compared to the UC intervention strategy.

We recognize some of the limitations in that we based our model on the data from a local study on the implementation of the CCM. No computational simulation model can perfectly represent reality, and all models have inherent limitations [**28**]. Interpretation of this study results will be based on model

assumptions. Subjects in the CCM study were representative of the population with diabetes in an underserved urban, suburb community, and thus generalizing the results to other populations or health care settings may be limited. When long-term information from the CCM study is not available, computational modeling may be used to integrate evidence from short-term clinical trials to make inferences about future economic, quality of life, and clinical outcomes and to provide data for decision making. However, the predictions provided by a model would depend on the clinical trial itself and the assumptions made in the model simulation. In addition, our study considers costs from the perspective of a health care system. Because of data limitations, the model did not include non-medical costs, such as lost productivity and the time provided by family and friends in caring for patients with diabetes. Thus, our model may underestimate the social costs of diabetes, subsequently affecting the estimated cost-effectiveness ratios.

This evidence is being presented to health care decision makers for them to consider approaching chronic disease management within a new paradigm.

Objective 3. Report on effectiveness of telemedicine endocrinologist initiative

Background

It has been projected that there will be between an 8-25% mismatch between supply and demand for endocrinologists by the year 2010. In Pennsylvania, there is a 22% vacancy rate in endocrine practices, the highest rate for any specialty [**29**]. Because of increasing rates of diabetes and complexity of care issues, the demand for endocrinologist services has risen. Most communities, however, do not have access to these services. Video-conferencing capabilities allow health care practitioners to engage in virtual face-to-face encounters with patients or other health care providers. In providing outreach, we proposed a pilot project that links endocrinologist services to practitioners and patients cared for through the PRIDE UPMC Northwest Hospital. Since the DOD is also experiencing increasing rates of diabetes and a lack of specialty services, specifically endocrinology, we will use this demonstration project to:

1) Address alternative methods for enhanced care delivery; specifically telemedicine for diabetes specialist consultation
2) Determine technology requirements for the intervention
3) Evaluate patient, PCP and endocrinologist satisfaction of telemedicine technology for the delivery of specialist diabetes services to an underserved rural area
4) Determine if using video-conferencing telemedicine technology for the delivery of specialist diabetes services will improve access to specialty care for persons with diabetes in rural communities

Methods

The CCM was used as a framework for establishing the endocrinology telemedicine project design. Video conferencing for endocrinology consultation served as the system redesign. Elements of the CCM are integrated into the telemedicine framework as follows:

Community

A rural **community** in Northwestern PA was established as the outreach area for the telemedicine pilot project. Venango County is a rural county located in northwestern Pennsylvania (PA) with an estimated population of 57,098. According to the PA Department of Health, the estimated number of people with diabetes in Venango County is 2,816 [**30**]. In addition, Venango County has one of the highest rates of hospital admissions for diabetes in the state with greater than 21.0 per 10,000 residents requiring diabetes inpatient care [**31**]. Currently there is one endocrinologist, working an average of one day per week, serving Venango County residents. This limited access to specialty services leaves the burden of care for patients with diabetes on the primary care practices. Venango County is served by one acute care hospital, UPMC Northwest located in Seneca, PA.

From a cohort of 4 UPMC Community Medicine, Inc. (CMI) primary physician practices, 8 practitioners from the local rural **community** were identified to participate in the project.

Health System

UPMC **health system**, University of Pittsburgh Division of Endocrinology Division, serves as the hub site for specialist endocrinologist services. Dr. Frederico Toledo, MD, Co-Investigator is Board Certified in

both Internal Medicine and Endocrinology and Metabolism. He has several years of experience working in research of human physiology of diabetes and obesity and has been in clinical practice since 2004.

Decision Support

PCPs establish patient treatment goals with **decision support** provided by the endocrinologist. The endocrinology specialist provides expertise in practice, management and treatment of diabetes.

Delivery System Redesign

A new model of care delivery is established by utilizing videoconferencing technology to link endocrinologist specialist services to practitioners and patients in rural communities [**32**]

Clinical Information Systems

Patient laboratory data is accessed by the UPMC Northwest clinical data repository known as Clinistar. Access to laboratory data serves as a mechanism for the UPMC Northwest Program Manager to gain information on performance and results for participating PCPs. This system allows UPMC Northwest administrators and providers to identify needs for practice and health system changes to improve diabetes care.

Self- Management Support

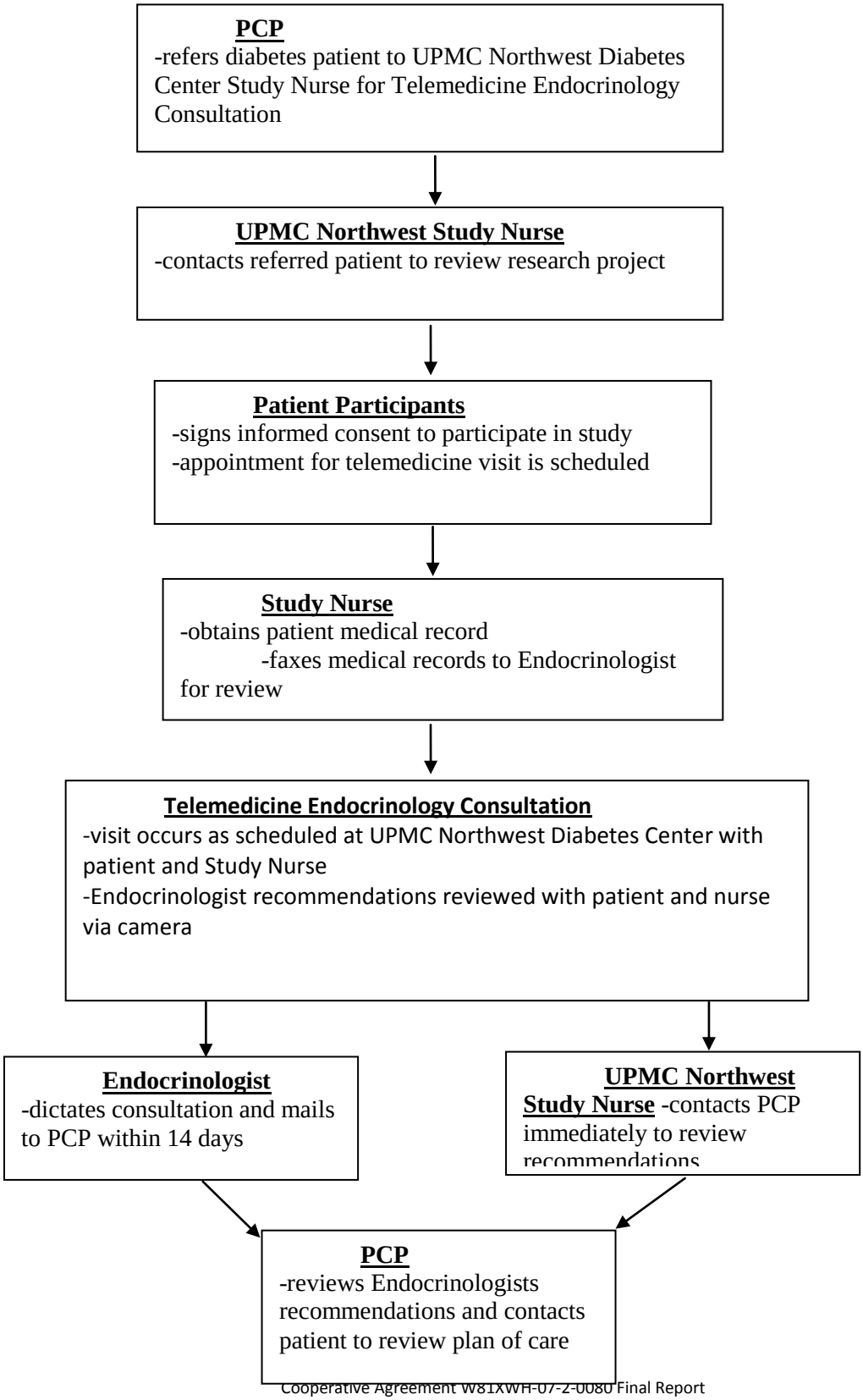
UPMC Northwest Diabetes Education Center provides self management support services. Amy Uhler RN, BSN, program director and study nurse, served as the liaison between patients, PCPs and the endocrinologist. Patients are referred to the UPMC Northwest Diabetes Education Center for DSME services and MNT. Services are provided by a certified diabetes educator.

Intervention

A pilot study to deliver endocrinology consultation via teleconferencing was conducted over 18 weeks with diabetes patients from rural Venango County. We collaborated with Falk Clinic (hub) and UPMC Northwest PCPs and the Diabetes Center (spoke) to provide facilitation of telemedicine consultation visits. A video-conferencing system was placed in the hub and spoke sites. The systems were located in clinic areas, where the endocrinologist and nurse could easily perform other duties between visits.

Adults
Chronic Care Model
Civilian Populations

Project processes are outlined in the following flow chart:



Analysis

The statistical analysis incorporates both descriptive and inferential techniques. The distribution of and descriptive statistics for all variables of interest was performed to determine distribution, mean, median, and other characteristics necessary to determine appropriate statistical analyses to be performed.

Results

After participating in the telemedicine program, patients were asked to complete a survey with 8 questions regarding their satisfaction with the experience. Answers on a Likert scale ranged from 0 (dissatisfaction/disagree/not recommend) to 6 (very satisfied/strongly agree/definitely recommend). Additional comments are included.
The following table presents the responses of the 25 patient participants completing the survey:

Table 1.

1) **Have you ever been told you should see the Endocrinologist?** 14/Yes 11 / No
2) **Have you ever had a visit with the Endocrinologist?** 6/ Yes 19/No
3) **If you Doctor asked you to see an Endocrinologist how far would you be willing to travel to see the Endocrinologist?** 7/10 miles 7/ 50 miles 10/Distance doesn't matter 10/Distance doesn't matter 1/ Unable to travel
4**) How satisfied were you with communication and asking questions in the Endocrinology visit through video conferencing**? All reported high to very high satisfaction "Neat, easy and informing."; "It was cool easy to understand."; "Wonderful way to connect with a quality doctor."; "Really great for people who don't like to travel or have to go a long distance to see a specialist."; "Glad to have peanut butter explained, as I was doing the wrong thing."; "Very helpful."; "Doctor was an exceptional listener".
5) **How satisfied were you with the video conferencing method for the Endocrinology visit?** All reported high to very high satisfaction "Make it a little easier to hook up with charge nurse"; "I think the quality of my care will be greatly improved"; "It's nice to be able to see the doctor and he can see me"; "Nervous at first, but as video continued, I became calm and interested in the questions asked"; "Once or twice the doctor and I "stepped" on each other's words".
6) **How satisfied were you with the technology (eg: sound and picture) in the video conferencing Endocrinology visit?** All reported very high satisfaction "Definitely recommend this to everyone, very clear and clear sound".
7**) Would you recommend this form of treatment to someone else with diabetes?** All reported likely to definitely recommend
8) **Would you recommend this form of treatment for other specialty care services?** All reported recommending

After participating in the telemedicine program, PCPs were asked to complete a survey with 17 questions regarding their satisfaction with the experience. Answers on a Likert scale ranged from 0 (dissatisfaction/disagree/not recommend) to 6 (very satisfied/strongly agree/definitely recommend). One of the physician participants refused to complete the survey without reason.
The following table presents the responses of the 7 primary care physician participants completing the survey:

Table 2.

1) **How would you rate your overall satisfaction with the diabetes telemedicine program?** All reported high to very high satisfaction
2) **The endocrinologist and I were able to effectively communicate a treatment plan together?** 6 reported high to strong agreement, 1 reported agreement
3) **Our roles in the management of the patient were clear.** 6 reported high to strong agreement, 1 reported agreement
4) **The study nurse and endocrinologist were very helpful in facilitating the consultation?** 6 reported high to strong agreement, 1 reported agreement
5) **Communication was passed between specialist and my office efficiently.** 5 reported high to strong agreement, 1 reported agreement, 1 reported disagree
6) **I was able to know my patients' needs in the context of their diabetes.** All reported high to strong agreement
7**) I was assured that I would provide continuity of care to my patients with diabetes.** All reported high to strong agreement
8) **This telemedicine service affords increased access to patient referrals to specialty areas.** All reported high to strong agreement
9) **I value the information from the study endocrinologist.** 6 reported high to strong agreement, 1 reported agreement
10) **Our roles in the management of the patient is clear to me.** 6 reported high to strong agreement, 1 reported agreement
11) **I received timely information from the endocrinologist.** 6 reported high to strong agreement, 1 reported disagreement
12) **The most recent management strategies are applied to patients with diabetes** All reported high to strong agreement
13) **I feel I am achieving worthwhile results through my work in diabetes patient management.** 6 reported high to strong agreement, 1 reported agreement
14) **My patients with diabetes appreciate that I can offer specialty services.** 6 reported high to strong agreement, 1 reported disagreement
15) **How likely would you be to use this program again?** 5 reported much more likely to recommend, 2 reported less likely to recommend
16) **Would you recommend this form of program to other colleagues?** 5 reported likely to definitely recommend, 1 reported recommend, 1 reported not likely to recommend
17) **Would you recommend this form of treatment for other specialty care services?** All reported likely to definitely recommend

After participating in the telemedicine program, the Endocrinologist was asked to complete a survey with 9 questions regarding satisfaction with the experience. Answers on a Likert scale ranged from 0 (dissatisfaction/also disagree/not recommend) to 6 (very satisfied/strongly agree/definitely recommend). His additional comments are included.
The following table presents the responses of the endocrinologist completing the survey

Table 3.

1) **How would you rate the overall satisfaction with the diabetes telemedicine program?** Very satisfied "I was very pleased to help patients in need. Very organized work flow."
2) **How technologically difficult was the program (technology) to operate?** Very satisfied "Easy system, as long as you are comfortable with technology and video-conferencing."
3) **The primary care physician and I were able to effectively communicate a treatment plan together.** Highly agree
4) **Our roles in the management of the patient were clear to me.** Highly agree
5) **The study nurse and primary care physician were very helpful in facilitating the consultation.** Strongly agree
6) **Communication was passed efficiently between you and the primary care team.** "Unknown. I don't know how well they were received, on my end, I had problems delivering the recommendations."
7) **How likely would you use this program again?** Much more likely to recommend
8**) Would you recommend this form of program to other colleagues?** May not recommend "I would recommend only to selected colleagues who understand very well the challenges of the rural community. I would not recommend to colleagues who are not 'tech-savy'."
9) **Would you recommend this form of treatment for other special care services?** **Recommend** "It depends on the specific needs of the specialty. For instance, if the specialty is highly dependent on physical exam, I would not (e.g. cardiology). If the specialty is not dependent on physical contact (e.g. psychiatry), then I would. Even with the same specialty, this system may work well for certain disease, but not all of them."

The following is a summary of the endocrinologist's experience with this project:

Audio-visual equipment reliability: the system was found to be quite reliable during the visit encounters. There were no instances of disconnection in which patients could not be seen. Video quality was acceptable. Audio quality was acceptable and appeared to be so both directions (i.e. patient-to-physician and physician-to-patient.) I encountered some difficulty with patients that had hearing-impairments.

Areas for improvement: the quality of video and audio should continue to improve as the underlying technology improves.

Work-flow: it was extraordinarily efficient. No issues of concern at the hub (UPMC Falk-clinic) or at the spoke (UPMC-Northwest). From a resource utilization perspective, the endocrinologist concluded that adequate support staff at the hub and spoke sites *is absolutely essential* to coordinate the transfer of information and materials between the two sites before and after the patient encounter. This coordinated exchange must happen in a timely manner. This is not an issue in real physical visit encounters, but in Telemedicine it is an issue because of the geographic separation between the patient and physician and staff at both sites.

Areas for improvement: the quality of faxed tests/labs was variable and delayed data analysis in some encounters. The system may improve if the information could be transmitted electronically, instead of scanning/fax whenever available.

Patient mix: cases were very challenging and quite appropriate for the working model of telemedicine consults for patients in need.

Areas for improvement: none really, since all patients seemed to be quite appropriate referrals.

Ability to deliver adequate diabetes care: the endocrinologist felt comfortable assessing each diabetes case and the nature of the problems hampering glycemic control in all patients.

However, proposing long-term treatment plans was hampered to some extent, because of the one-time nature of the consultations. Knowing that patients would not return for reassessment called for extra caution, and perhaps less intense treatment recommendations.

Areas for improvement: return visits are necessary to assess how the telemedicine model works for a chronic disease.

Frequency of use

25 patient participants used the telemedicine endocrinology service, 8 PCPs and 1 endocrinologist, 1 patient had a 6 week follow up visit for a total of 26 visits

Summary

Through our feasibility study, we were able to demonstrate that patients, their PCPs and the endocrinologist and would recommend endocrinology consultation visits using video conferencing were highly satisfied.

Our goal was to recruit more patients into the study however we were limited by the following:

- This was originally planned to serve as a quality improvement project. However after further review, it was determined that it required full-board review, thus extending the timeline for recruitment.
- We organized efforts to host this program with Indiana Regional Medical Center (IRMC). After the program plans were in place, IRMC engaged the services of a part-time endocrinologist, negating the need for a telemedicine approach. Determining and engaging a new site required additional time.
- IRB approval required signed patient informed consent. Patients in far-reaching rural communities needed to make an additional trip to the center to sign the consent. This limited recruitment opportunities.
- The rural site requested that the endocrinologist become certified to provide care for the rural patients. This was later resolved (endocrinologist not required to obtain rural certification) however this also involved further delays.

We now appreciate the need for additional time in facilitating translation research projects like telemedicine. Logistical processes, like IRB and any unanticipated IRB requirement, need to be attended to in the planning process. Translation research lends itself to an uncontrolled, ever-changing social environment. Although the unanticipated employment of the endocrinologist was unforeseen, again careful planning with extended time needs to be considered.

In summary, UPMC and its PRIDE partners value the telemedicine approach and recognize the importance of further study. From our pilot work we learned that patients with T2D in this rural community referred for specialty services were at high risk. The mean HbA1c of this patient population was 9.8% (range 7.4-14%) at baseline. We also realized that a single visit using a telemedicine model can be successfully employed to answer specific questions on diabetes management. However, diabetes is a chronic disease and requires periodic follow-up visits to adjust therapy. The feasibility of having periodic visits and longitudinal compliance was not assessed. This is an important investigational step, because the long-term sustainability of the telemedicine model for diabetes care depends on patients returning to subsequent visits for therapeutic optimization. In addition, to test the efficacy of any telemedicine model of diabetes care, it is necessary to collect long-term data on clinical outcomes. We believe that telemedicine services can successfully provide continuity of care and produce improvements in clinically-relevant diabetes outcomes.

Currently, reimbursement for telemedicine services is limited to specific designate rural communities through Medicare and private insurers who determine a need and mechanism for telemedicine. Efforts to support telemedicine reimbursement are underway and reform will be based on demonstration of its benefit in the management of chronic disease states. Therefore, we recommend further study of the feasibility and compliance with multiple telemedicine visits, the impact on selected clinical outcomes, barriers to sustained care, and use of an assessment model of multiple periodical visits to adjust therapy.

Objective 4. Report on effectiveness of technology-based education program to extend the reach of the educators beyond the major medical facilities

Background

Goals set for Healthy People 2010 are to increase those reached with diabetes education from 40% (1998) to 60% (2010) [**33**]. Although the benefits of DSME have been widely accepted, participation rates are disappointing in that only one-third to one-half of US patients with diabetes receive DSME [**34**]. In PA, achievement of the education objective lags behind other Healthy People 2010 goals [**35**].

Research demonstrates the benefits of DSME. Patients with diabetes who do not receive DSME are found to be more likely to develop a major complication [**36**]. In our review of 17,346 diabetes patients who were hospitalized at the UPMC in 2004 and followed longitudinally through 2008, only 13% had received DSME services. These patients were already in poor health (had ICD9 codes for hypertension, myocardial infarction, coronary artery bypass graft, neuropathy, micro/macro albuminuria, dialysis, or kidney transplant) and incurred highest health care charges [**37**]. These data reaffirm the need for improvement in DSME services.

The numbers of patients who receive DSME are disappointingly small [**36, 37**]. Access to education has been posed as a barrier. It is reported that there are only 14,000 certified diabetes educators in the US. With the growing numbers of diabetes patients, efforts to expand the reach of educators are critical.

We, and others, have shown that patients hospitalized with diabetes receive little education during their hospital stay and are not routinely referred to outpatient DSME programs at hospital discharge. Also, providing education during a hospital stay is not a setting that provides a "teachable moment" [**38**]. To add to this challenge, in the outpatient setting, physicians are expected to refer diabetes patients to a DSME program, yet we and others have shown that physicians don't routinely refer patients for DSME until they already have co-morbidities and complications [**11**].

Although inpatient education services have been shown to be of value [**39**], hospital administrators are reducing nursing and educator staff as cost-cutting measures in an era of economic challenges. Outpatient DSME programs are also reporting closings, many because of low referrals [**19**].

In an effort to provide DSME survival skills for those patients hospitalized with diabetes (newly diagnosed or hospitalized with diabetes complications), we explored a technological approach and developed DSME DVDs to be given to inpatients at discharge. A major focus of the DVD program is to provide survival skills for safe transition to home, and also deliver messages directing patients to schedule a follow-up visit for DSME service.

Research also shows that many educators perceive physician referrals to be a key motivator for patients to attend DSME. Physicians report that more patients would be referred to DSME if the referral process was easier. In an effort to increase the number of referrals for DSME from the primary care setting, we have implemented a system in which appointments for DSME are scheduled with patients at the conclusion of their primary care visit.

An additional problem that has been reported is that there is often a long wait time before the patient can be seen for their DSME appointment. This may be why patients do not return for their scheduled

appointment, as often times patients either fail to remember their appointment or no longer feel education is necessary to their self-care. To remedy this problem, we also explored the use of the DVD program in the primary care setting to help increase awareness for DSME and thus encourage patients to attend their scheduled appointments.

The objectives are as follows:

1) Develop primary content that consists of video, animation, and text on diabetes self care behaviors
2) Gain feedback to refine content and format of technology-based education program/tool
3) Train facilities in use of technology-based education program/tool
4) Disseminate technology-based education program/tool for patient use at home
5) Track enrollment in outpatient DSME as a result of the dissemination of technology-based education/program tool
6) Compare user satisfaction on technology-based education program/tool to standard practice education

Methods

Development of the DVD Tool

A 50-minute DSME video was developed in DVD format. Diabetes educators at UPMC, PRIDE and WHMC, all of whom have expertise in the field, reviewed, validated and refined the content of the video scripts. A representative from the National Diabetes Education Program (NDEP) also reviewed the script and provided input.

DVD Tool

The DVD provides patients with basic diabetes survival skills to help manage their diabetes until they can be seen for outpatient DSME. The DVD was designed to engage and empower patients to take on a greater role in their own self-management and encourages them to attend DSME. This message is consistently reinforced through both copy delivered by the actors and visuals incorporated into the video.

The DVD is organized into chapters, each delivered by actors of varying genders, ages and ethnicities and employs the use of sound and graphical animation. Chapters include:

- What is Diabetes?
- Eating & Activity
- Medication
- Blood Glucose Monitoring
- Giving Yourself Insulin
- Low/High Blood Glucose
- Sick Day Management
- Coping with Diabetes
- Finding Support
- Your Next (Doctor) Appointment

Packaging

The DVD packaging, which also includes a business card and a patient satisfaction survey, is designed to be engaging and user-friendly. Through the use of a simple 3-step process, the patient is encouraged to 1) watch the DVD, 2) call the number on the attached business card to connect to an educator who will enroll them in education and 3) return a patient satisfaction survey regarding the helpfulness of the DVD.

Support Person Brochure

A support person brochure is also included in the packaging. The brochure is targeted to a member of the patient's support team, e.g. a spouse, sibling, caregiver, etc. The brochure explains to the support person the importance of watching the video with the patient so that they can provide assistance and support.

Training

We met with each PRIDE manager to introduce the DVD program and determine their method for distribution.

Distribution (Settings)

Inpatient

DVDs were distributed, in an inpatient setting, at several PRIDE locations. All are representative of small, rural community hospitals in southwestern PA. They include:

- Highlands Hospital
- Indiana Regional Medical Center
- Uniontown Hospital

Primary Care

Centerville Clinics, a PRIDE partner, is a large network of federally-qualified medical clinics where diabetes educators travel between the various locations for DSME. It has been reported by educators and office staff that there is usually a long wait before a patient can be seen for DSME, and patients subsequently do not show up for their previously scheduled appointment ("no shows").

Thus, the DVDs were distributed and a DSME appointment was made by office staff at the close of the patient's appointment with their PCP. While the DVD helps to ensure that the patient has the basic survival skills to assist them in managing their diabetes at home, it also helps to underscore the importance of patient participation in diabetes education and encourage them to attend their appointment for DSME.

Table 4.

	Method for Distribution	
	Distributor	**Setting**
Highlands Hospital	Diabetes educator	Inpatient
IRMC	Diabetes educator	Inpatient
Uniontown Hospital	Staff nurses	Inpatient
Centerville Clinics	Staff scheduling outpatient DSME appointments	Primary Care

Data Collection

Monthly Reporting Form

PRIDE partner managers were asked to complete a monthly reporting form, from August 1, 2009 through November 15, 2009 that includes the following questions:

1. "How many DVDs were distributed this month at your location?"
2. "How many patients attended outpatient DSME at your location this month?"

The number of patients seen for outpatient DSME from August through November in 2008 were counted and compared to the same time frame in 2009 to see if the DVD program helped increase the number of patients enrolled in outpatient DSME.

The number of patients who did not attend their previously scheduled appointment for outpatient DSME at Centerville Clinics from August through November in 2008 were counted and compared to the same time frame in 2009. This was designed to determine if the DVD helped increase awareness for DSME and encourage patients to attend their scheduled appointment.

Educator Satisfaction Survey

To determine diabetes educator satisfaction, a survey was developed and administered to all PRIDE diabetes educators involved in the project. The following questions were designed to capture answers relevant to the technical objectives. Educators were asked to answer "yes" or "no" to the following questions:

1. Did you find the DVD to be useful in preparing patients for DSME?

This question was asked to determine if the content was found to be useful in providing patients with the survival skills.

2. Do you think this DVD extends your reach and helps drive patients to DSME?

The DVD serves to extend the reach of the diabetes educator.

3. Do you think this DVD communicates the importance of patient participation/engagement in a diabetes self-management education program?

Traditionally, standard practice of diabetes education has been communicated to be participation in a didactic class.
We wanted to learn if a technology-based education tool is effective in conveying the importance and increasing awareness for patient participation in DSME. The DVD was designed to engage and empower the patient to take on a greater role in their own self-management.

4. Would you recommend this DVD to a colleague?

It has been shown that there is a strong correlation between product loyalty and answering the question "Would you recommend this product to a friend or colleague?"

Patient Satisfaction Survey

In an effort to determine patient satisfaction with the DVD program, a survey was developed and included in the DVD packaging. The questions in the patient satisfaction survey are as follows:

1. "How helpful was the video in giving you a better understanding of how to care for your diabetes?" ("not at all helpful", "somewhat helpful", or "very helpful")
2. "What section of the video was most helpful to you?" (open-ended response)
3. "Is there anything else that you wish was included in the video?" (open-ended response)
4. "After watching the video, how confident do you feel in caring for your diabetes?" ("not at all confident", "somewhat confident", or "very confident")
5. "Would you refer this video to a friend with diabetes?" ("yes" or "no")
6. "The video emphasized the importance of enrolling in the Diabetes Self-Management Education class. Have you gotten the referral from your doctor and registered for the class yet?" ("yes" or "no")
    - "If no, do you plan to register for the class?"
    - "If no, please explain why"

Analysis

This project was reviewed and determined that it did not require IRB approval.

To determine if the DVD had an effect on the number of patients attending DSME, frequencies were analyzed based on the monthly reporting forms. The number of DVDs distributed at each location during the designated time frame were counted. The number of patients who attended outpatient DSME in months August-November 2009 was compared to the number of patients who attended outpatient DSME in months August-November 2008 to accommodate any temporal influences.

Results

DVD Distribution

From August 1, 2009 through November 15, 2009 a total of 254 DVDs were disseminated through the four PRIDE partners.

Table 5.

	Aug	Sep	Oct	Nov	Totals
Highlands Hospital	10	5	20	11	46
IRMC	24	14	13	2	53
Uniontown Hospital	17	10	40	4	71
Centerville Clinics	27	20	32	5	84

Enrollment in Outpatient DSME, Comparison of August through November in 2008 and 2009

As shown in Figures 18-20 below, PRIDE partners reported increases in the number of patients enrolled in DSME as compared from 2008 to 2009 during the same time frame. The number of patients who did not attend their scheduled appointment (no shows) decreased at Centerville Clinics from 2008 to 2009 during the same time frame.

Figure 18.

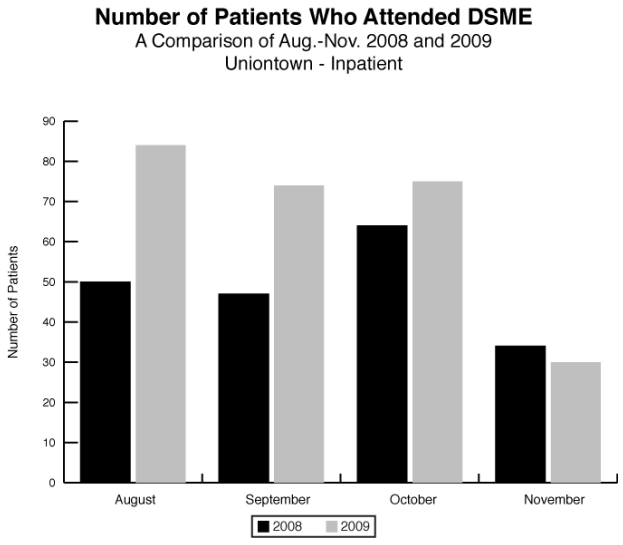


Figure 19.

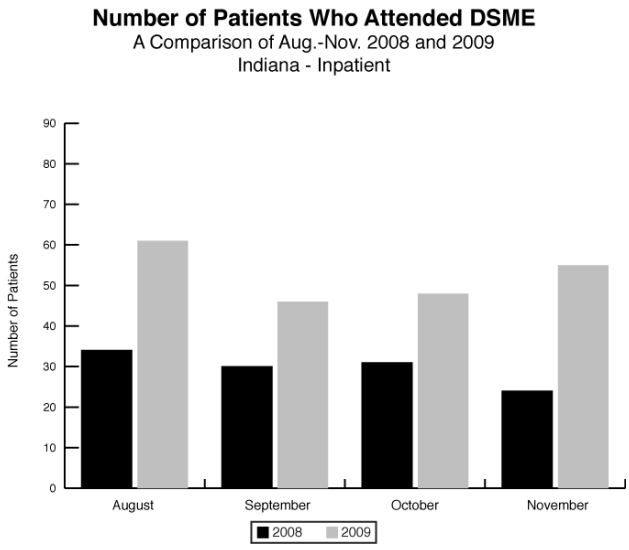
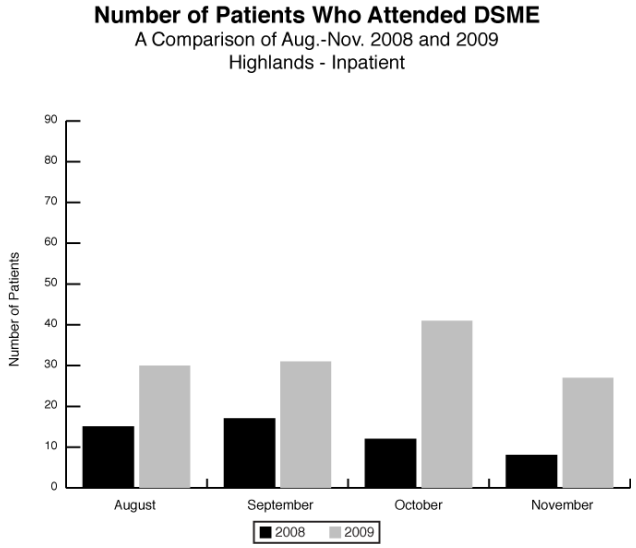
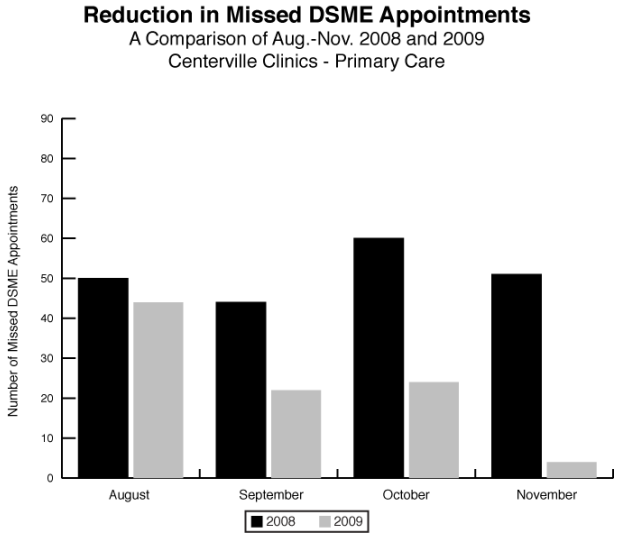


Figure 20.



602 patients were seen for outpatient DSME at the three PRIDE locations in 2009 (Figures 18-20), as compared to 366 patients who were seen for outpatient DSME in 2008 during the same time frame.

Figure 21.



The number of patients who did not attend their previously scheduled appointment for outpatient DSME at Centerville Clinics from August through November in 2008 was counted and compared to the same time frame in 2009 (Figure 21). This was done to determine if the DVD helped increase awareness for DSME and encourage patients to attend their scheduled appointment. 205 patients did not attend their scheduled DSME appointment at Centerville Clinics in 2008, as compared to 94 patients who did not attend their scheduled DSME appointment in 2009.

Educator Satisfaction Survey

Satisfaction surveys were returned by all of the diabetes educators from the participating PRIDE locations. All of the educators reported high satisfaction with the DVD tool. In summary, the diabetes educators reported that:

- The content was useful in providing patients with the survival skills needed to manage their diabetes at home until they could be seen for outpatient DSME.
- The DVD helped extend the reach of the educator and encouraged patients to attend DSME.
- A technology-based education program is effective in conveying the importance and increasing the awareness for patient participation in diabetes education.
- They would recommend the DVD, therefore showing a strong degree of satisfaction for the DVD.

Patient Satisfaction Survey

The patient satisfaction survey was included in the DVD packaging. The return rate was low, thus we determined that due to the low response we would not be able to draw relevant conclusions from the patient surveys. Of those that were returned, the patients favorably reported:

- The video was "very helpful" in giving them a better understanding of how to care for their diabetes.
- Feeling "somewhat confident" or "very confident" in caring for their diabetes after watching the video.
- They would refer the video to a friend with diabetes.
- They already sought a referral from their physician to attend the DSME class.

Summary

Based on our results, we conclude that the DVD played a valuable role in increasing the number of patients enrolled in DSME and extended the reach of diabetes educators. We suspect that by distributing the DVDs in the primary care setting, patients were also more inclined to attend their scheduled DSME class.

We recognize that other programmatic efforts, apart from the DVDs, could account for the increase in outpatient DSME participation. However to our knowledge no other efforts to extend or market educational programs were going on at the time of study in these communities. We were made aware that some patients had limited access to a DVD player in some underserved regions within the study area and that the educators were not always consistent in distribution of the DVDs. We were disappointed in the low rate of return for the patient satisfaction survey, however, we appreciate that return rates on questionnaires are usually low unless linked to an incentive.

Educators reported high satisfaction with the program in that the DVD helped to extend their reach, helped to prepare patients for DSME and increased awareness for patient participation in DSME. Based on our findings, we conclude that the DVD technology program has the potential to be a useful tool in filling the gaps between inpatient and outpatient education and offers support to extend the reach of the diabetes educator. Continued study of the process is recommended and efforts to address limited availability of technology systems for those in underserved populations needs to be addressed.

Military Populations

The University of Pittsburgh Medical Center (UPMC) with its Air Force (USAF) partners have taken steps to implement the Chronic Care Model (CCM) into their respective networks to improve diabetes care processes and outcomes in its practice settings. The CCM, organized around elements that have been shown to improve outcomes, has been used throughout the diabetes project as a framework to guide delivery of services and for record of adoption.

In a meta-analysis of diabetes quality improvement efforts, programs that addressed team changes showed more robust improvements in glycemia than any other strategy [**40**]. The importance of a team approach in diabetes care has been repeatedly demonstrated however it is often unavailable in primary care [**40-42**]. Thus, the Diabetes Outreach Clinic (DOC) was first established to facilitate a team approach for patients with diabetes to improve glycemia while offering primary care services during a clinic visit. The DOC, staffed by a multidisciplinary team, was established by the UPMC at the direction of the USAF medical team to provide comprehensive primary and specialty care to patients with diabetes at WHMC. The DOC began operations in January, 2006 and was subsequently transformed into the DCOE in January, 2009.

It was hypothesized that implementing the CCM for the USAF at WHMC (and additional future outreach sites) would ultimately result in improved patient clinical outcomes. In addressing all of the elements of the CCM, the investigative team worked on the following objectives:

1. Implementation of all elements of the Chronic Care Model at WHMC
2. Cost-effectiveness of the Chronic Care Model in a military population
3. Effectiveness of a technology-based educational program at WHMC

With the current shortage of diabetes specialists, including endocrinologists and diabetes educators, USAF leadership subsequently determined that a hub and spoke model would more likely serve as a sustainable model for the already stretched military team treating individuals with diabetes. The transition from the original DOC model occurred in January, 2009. The focus of this report is specific to the DOC, prior to the transition to the DCOE model; however, preliminary work regarding the DCOE is also presented.

The Comprehensive Diabetes Management Program (CDMP) is currently undergoing a DIACAP review to integrate the Joslin Vision Network (JVN) and Notewriter programs. UPMC has chosen not to use an AADE system due to challenges, which were reported to AF/SGR. Flipside Media and Estenda Solutions are having ongoing conversations about possible collaboration in using their respective tools.

Objective 1. Implementation of all elements of the Chronic Care Model at WHMC

Background

UPMC relied on its experience in deploying the CCM and worked to apply this framework at WHMC [**5**, **6**].

Methods

Elements of the CCM

The following elements serve as the framework to monitor adoption.

1) ***Health system*** serves as the foundation by providing structure and goals

2) ***Community*** is used to directly link the hub with community resources

3) ***Decision support*** serves to assure that providers have access to evidence-based guidelines

4) ***Self-management support*** helps patients acquire skills and confidence to self-manage

5) ***Clinical information systems*** provide timely access to data about patients and populations

6) ***Delivery system design*** is used to restructure medical practices to facilitate team care

Health System Organizational Support

AF representatives worked with UPMC to outline plans for implementing the DOC and the CCM at WHMC. UPMC staff at WHMC and University of Pittsburgh Investigators communicated with the Texas Department of Health to gather information on the Texas State Diabetes Plan. The Texas Plan was reviewed to explore synergies with the CCM efforts ongoing in Western Pennsylvania.

UPMC employed staff for the USAF DOC. The DOC was established early in the project cycle and served as a comprehensive clinic providing both primary and specialist diabetes care to patients. This was considered to be an innovative approach to the delivery of comprehensive care to people with chronic disease and information gained during the DOC implementation was evaluated.

Community

Focus groups were facilitated with both the patients and providers to address the needs of the military communities. Focus group participants were recruited through the local diabetes educators and primary care providers. Focus group questions were based on a script from the CCM. All discussions were audio-taped and subsequently transcribed. No identifying information was recorded. This work was done as part of a program development initiative by the Department of Defense (DOD) and as such did not require IRB approval.

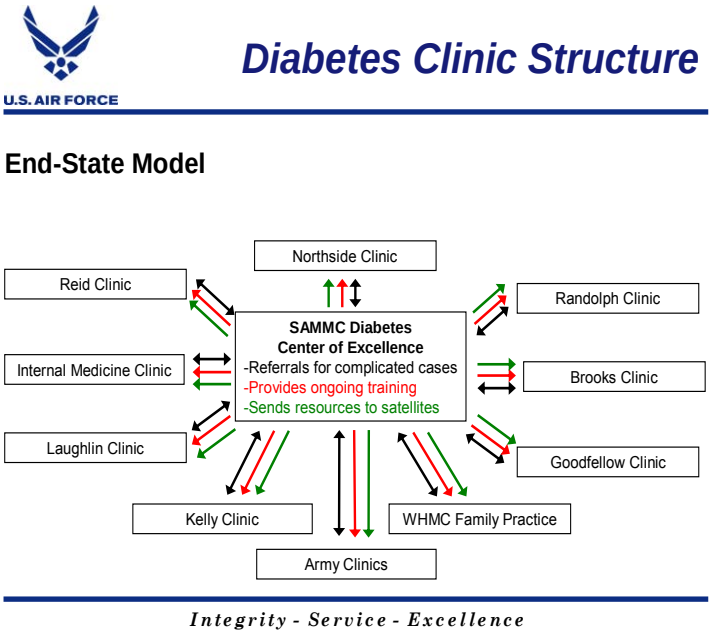
A focus group was conducted in the spring of 2008. This focus group was held with six patients recruited from the DOC and included 4 males/ 2 females.

Two focus groups were conducted at Goodfellow AFB in May 2008 by the UPMC team (Drs. Trauth and Terry). These groups included diabetes patients who attend the family medicine clinic and healthcare providers that take care of the individuals with diabetes.

Another focus group was conducted during the spring of 2009 for patients receiving care at Laughlin AFB.

The diagram depicted in Figure 1 presents plans designed by AF for program outreach.

Figure 1. Diabetes Clinic Structure



The overall goal for the outreach sites is to provide quality care for their respective diabetes patient population. Therefore, determining how many individuals with diabetes receive diabetes care services was a necessary first step. Table 1 lists the number of patients with diabetes who currently receive diabetes care services at the respective sites. These numbers were obtained from information gathered through the Health Care Integrators (HCI) at each base.

Table 1. Number of Individuals with known Diabetes, based on CPT Codes

Randolph AFB	639
Goodfellow AFB	135
Laughlin AFB	178

Each of the three bases was contacted by Drs. True and Wolf. Their discussions addressed the overall diabetes program and the possibilities for arranging a visit. Visits were scheduled with the "Go Team".

The following sites were visited:

Goodfellow AFB, March 2008 – "Go Team" Members: Lt Col (Dr.) Mark True, James Mason, Dr. Donna Wolf, Tanya Crail, and Jose Perez.

Laughlin AFB, April 2008 – "Go Team" Members: Lt Col (Dr.) Mark True, Ms. Watson, Dr. Donna Wolf, Jose Perez

Randolph AFB, May 2008 – "Go Team" Members: Lt Col (Dr.) Mark True, Tanya Crail, Jose Perez, Ms.Watson, James Mason

Randolph AFB, December 2009 - "Go Team" Members: Lt Col True, Ms. Watson, Ms. Naff, Ms. Kelly

Air Force Base Assessment

During the assessment, the "Go Team" assessed the facilities, number of available staff and software availability. The "GoTeam" reviewed the overall cooperative agreement, the elements of the CCM, plans for expansion based on the strategic planning documents, diabetes prevention program opportunities and software applications CDMP, JVN, Notewriter, AADE Outcomes).

Each base interested in participation was asked to:

- Identify diabetes champions at the respective base
- Participate in focus groups to identify key needs and potential barriers to effective diabetes care
- Share diabetes outcomes and metrics data routinely
- Begin to group diabetes appointments
- Identify specific information technology tools of interest
- Work with systems personnel to incorporate these tools into your practice

During the course of the project, a request was made to engage diabetes educators at Kelly AFB anf train them to take retinal images. Recruiting educators was problematic. Therefore, the DOC ophthalmologist and technician travelled to Kelly AFB on a regular basis to take and read patient retinal images.

Decision Support

The American Diabetes Association (ADA) Medical Standards of Care [**7**] and the National Standards for Diabetes Self-Management Education (DSME) [**8**] serve as the mechanism to assure quality and benchmarking for diabetes outcomes. The ultimate goal is to introduce local practitioners to the ADA Standards of Medical Care in anticipation of future efforts that involve the National Commission of Quality Assurance (NCQA) provider recognition program.

Clinical Information Systems

CDMP

The Comprehensive Diabetes Management Program (CDMP) is a software application used to help clinicians manage patients with chronic illnesses. CDMP was built in conjunction with the Joslin Diabetes Center, multiple clinical expert partners and the Estenda Co. This software system is designed to 1) capture diabetes patient data receiving care in the DCOE 2) provide healthcare providers with alerts and reminders 3) be used as a patient management tool 4) and be used for data entry and tracking. The current version of CDMP being used at WHMC is linked to ICDB. Data is imported (demographics, labs, medications, procedures, diagnosis and admissions) from ICDB into CDMP. Systems that help to define, measure and collect relevant data on education outcomes, that specifically include elements of behavior change were not available. Educators in the AADE (of which both UPMC and military educators are members) determined that comprehensive efforts in defining, measuring, collecting, and reporting of diabetes education outcomes for advancing the practice of DSME were needed. Both external environmental influences and organizational efforts converged in guiding the

activities that resulted in the AADE Outcomes Project. A description of the project activities, the components developed and their application to diabetes education practice are described in AADE/UPMC publications [**9**-**12**].

The AADE Outcome System was introduced to support self-management education processes. The AADE Outcome System was the first IT education system introduced and was later replaced with the comprehensive Chronicle data management program. Currently, the Chronicle application and synergies with CDMP are being explored.

Self-Management Support

The National Standards for DSME administered through the ADA recognition program provides the framework for quality education and reimbursement for services [**13**]. Medicare and other third-party payers reimburse for programs when they meet ADA requirements. Reimbursement is linked to codes, and charges are typically based on Medicare rates [**14**]. Reimbursement is critical in generating revenue to support nurse and dietician educators who provide DSME in order to bill for DSME, programs must meet the National Standards for DSME and be approved through the American Diabetes Association Recognition Program. Education charges are based on Health Care Common Procedure Coding System (HCPCS) "G" codes. We established mechanisms to achieve ADA DSME recognition and explored opportunities to bill for services after recognition was awarded. Disappointingly, Tricare has yet to integrate "G" codes into their billing systems. National efforts are underway to rectify this.

Delivery System Redesign

The DOC was a primary care clinic that served patients with diabetes. The criteria for enrollment into the clinic was patients aged 18-62 years who had an HbA1c level > 6.5%. The patient population represents all Tricare prime beneficiaries, which includes active duty, retirees and dependents. The patient empanelment was divided between two UPMC healthcare providers, an Endocrinologist and a nurse practitioner (NP). The DOC clinic operated under a "one stop shop" concept, where clinic patients had access to multiple health care providers at one visit. In addition to a visit with their provider, patients were also able to see a dietitian, nurse educator, counselor and/or ophthalmologist. A typical initial patient visit included a one hour visit with their provider, followed by a 30 minute session with the nurse educator and a 30 minute session with the dietitian. If an annual eye exam was required, the patient also visited the ophthalmologist.

Figure 2. Patient Appointment Template

Nurse Practitioner		Endocrinologist	
8:00	Initial appointment	8:00	Initial Appointment
9:00	Initial appointment	9:00	Initial Appointment
9:30	Follow-up	9:30	Follow-up
10:00	Follow-up	10:00	Follow-up
10:30	Follow-up	10:15	Follow-up
11:00	Follow-up	10:30	Follow-up
11:30	Acute	10:45	Follow-up
11:45	Acute	11:00	Follow-up
1:00	Initial	11:30	Acute
2:00	Acute	11:45	Acute
2:15	Acute	1:00	Initial
2:30	Follow-up	2:00	Acute
3:00	Follow-up	2:15	Acute
2:30	Follow-up		
3:00	Follow-up		
3:30	Follow-up		

Following an initial exam visit, the provider scheduled follow-up visits. Patients who were considered to be in good diabetes control (HbA1c < 6.5%), were routinely followed by their provider in the DOC every three months. Some patients, i.e. patients with multiple medical problems, uncontrolled diabetes or needing medication titration were followed more frequently.

Drop in Group Medical Appointments (DIGMA) at the DOC

UPMC staff used the DIGMA approach as a means of increasing the number of available appointments. As reported to AF/SGR:

Research has suggested that patients benefit from participating in a DIGMA. Researchers have used surveys to demonstrate high satisfaction in patients that attend DIGMA's. It has been established in work executed by Dr. Edward B Noffsinger that patients have accepted DIGMAs well and actually prefer DIGMAs to traditional office visits. Researchers deem that DIGMAs empower patients by giving them choice while giving assurance that individual appointments can also be scheduled as before.

Some advantages documented by Dr. Noffisinger are as follows:

- *Reduced loneliness*
- *Peer education*
- *Slower pace*
- *Increased satisfaction*
- *Guideline implementation and adherence*
- *Increased time with provider.*

DOC staff were formally trained on the DIGMA model in March 2006 by Dr. Noffsinger, an expert on group medical visits. The DOC providers first implemented the DIGMA in September 2006. Using the DIGMA model, 8-10 patients in a group were seen by the endocrinologist one morning per week while 6-

8 patients in a group were seen by the nurse practitioner one afternoon per week. Each group medical appointment lasted 90 minutes. Each provider would determine the patients to schedule for their weekly group. Typically, patients were seen in the group appointment for a variety issues that needed to be addressed: medication titration, acute illness, etc. The counselor, dietitian, diabetes educator, ophthalmic technician and preventionist would participate in the group process on an ongoing rotating basis.

As previously reported:

Prior to the start of each appointment, each patient is required to sign a confidentiality statement to ensure that each patient's HIPAA rights are protected and that the information discussed in the room is kept confidential. Family members that attend with the patients are also required to sign this confidentiality form.

The DIGMA greatly improves patient access to care at the DOC, which in turn should increase patient satisfaction. The provider normally sees 2-3 patients within a 90 minute timeframe. However, in the DIGMA setting the physician sees 10 patients while the CRNP see 6 patients. Therefore, DIGMA increases patient access to care 300% for the physician and 200% for the CRNP.

The DOC held weekly DIGMAs from September 2006-August 2008.

Delivery System Redesign

As noted, the DOC held DIGMA sessions weekly from September 2006 until the endocrinologist, Dr. Baquero, departed in August 2008. The DCOE staff opted to discontinue the DIGMA model.

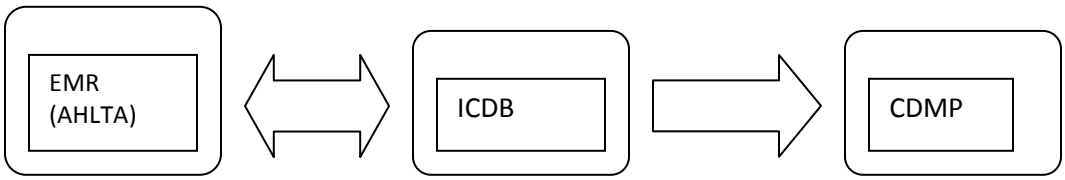
The DIGMA was not continued for the following reasons:

- Endocrine staff did not find it to be an effective model for specialty care. They agreed that DIGMA concept is more likely to be an effective model when providing primary care.
- It was reported that while some patients enjoyed the group appointment, there were many who were uncomfortable with the group approach. Patients stated that they did not want to share their medical information in a group setting, while others were uncomfortable being part of a group dynamic.

Measures

Clinical measurements are recorded by the healthcare providers in the patient's electronic medical records (EMR). The clinical metrics that are collected in the EMR are then pulled from both CDMP and Population Health (Figure 3). IRB approval was received for collecting this data.

Figure 3. Clinical Measures Collection



* Note CDMP is able to pull individual clinical data (i.e. lab values, demographic information, medical procedures, etc.) from ICDB database.

Analysis

Quantitative

We used descriptive statistics to examine the demographic characteristics of the patient population. All data was described with measures of central tendency. In univariate analyses, T-tests for continuous data and Chi Square tests for categorical data will be used to determine within group differences between baseline and follow-up visits.

Qualitative

Qualitative data are analyzed relying on central themes from focus group meetings based on a script using the elements of the CCM and "Go Team" input.

Results

During the DOC operation, 9,318 provider visits were facilitated from January 2006 through December 2008. Table 2 represents the number of each type of provider at the DOC.

Table 2. DOC Personnel

Endocrinologist	1
NP	1
Nurse Educator	1
Dietitian	1
Ophthalmologist	1
Ophthalmology Technician	1
Counselor	1
LVN	1
Medical Assistant	1
Front Desk Support	2

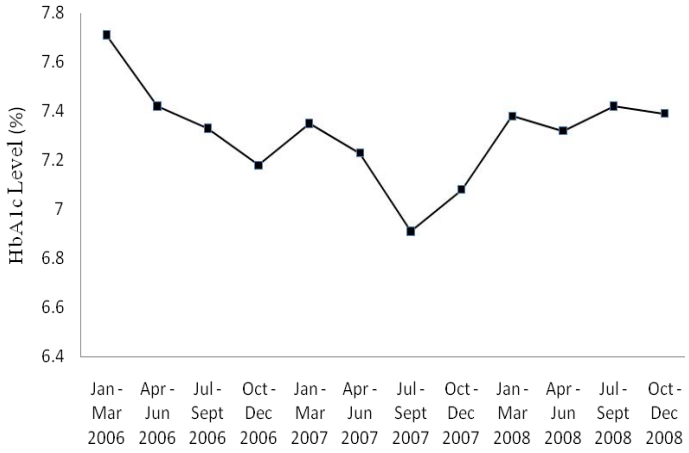
Table 3 represents the rate of patient attendance with specific providers. As shown, the majority of patients kept their appointments with DOC providers.

Table 3. Rate of Patient Attendance with Specific Providers

Provider	Percent Kept	Percent No Show	Percent Cancelled
Endocrinologist	79%	4%	17%
NP	76%	6%	18%

HbA1c is used to measure blood glucose control. Figure 4 represents mean patient HbA1c levels

Figure 4. DOC Patient Mean HbA1c Levels Analyzed Quarterly from January 2006-December 2008



The average patient baseline HbA1c level for those patients referred to the DOC was 7.8% when the clinic opened in January 2006. In the last report of patient mean values, HbA1 C dropped to 7.4% (December 2008).

The following tables (Table 4-6) represent data from 1,171 DOC patients. Footnotes explain missing data. We defined the records from 1 year prior to patients entering the DOC as the baseline DOC data, and all records after entry as the follow up-DOC data (last value).

Table 4. Descriptive Characteristics of the DOC Patients

Characteristic	DOC (n=1,171)		
	Baseline	Follow-up	P value[m]
Descriptive characteristics			
Mean age at study entry (SD), years	55.5 (9.2)	---	---
Gender, n (%)			---
Female	516 (44.1)	---	
Male	655 (55.9)	---	
Race, n (%)			---
White	370 (31.6)	---	
Non-White	193 (16.5)	---	
Missing	608 (51.9)	---	
Mean weight[a] (SD), kg	---	94.5 (21.8)	---
Mean height[a] (SD), cm	---	169.9 (10.9)	---
Mean BMI[a] (SD), kg/m^2	---	32.6 (6.3)	---
Insulin usage, n (%)			**<.001**
Yes	293 (25.0)	394 (33.6)	
No	874 (74.6)	774 (66.1)	
Missing	4 (0.3)	3 (0.3)	

[a]At follow-up, 19 (1.6%), 21 (1.8%), and 21 (1.8%) patients in DOC had missing data for weight, height, and BMI respectively. These missing data appeared when either no data (or unusual data) were recorded during the intake period or these measures were not captured in Military Health System.

[m]P value was derived from paired t-test or McNemar's test for comparing non-missing data between baseline and follow-up in each group. The null hypothesis for insulin usage was that the proportion of patients using insulin after intervention is not different from that before intervention. The null hypothesis for diabetes complications was that the proportion of patients with any diabetes complications after intervention is not different from that before intervention.

Table 5. Changes in clinical outcomes of DOC patients

Clinical characteristics	DOC (n=1,171)		
	Baseline	**Follow-up**	**P value[m]**
Mean A1C[b] (SD), %	7.8 (1.6)	7.2 (1.2)	**<.001**
Mean SBP[c] (SD), mmHg	129.8 (18.5)	131.4 (14.9)	.76
Mean DBP[d] (SD), mmHg	79.4 (10.1)	77.4 (8.9)	.29
Mean total cholesterol[e] (SD), mg/dL	176.0 (33.8)	164.4 (31.4)	**<.001**
Mean HDLc[f] (SD), mg/dL	48.9 (12.7)	47.9 (12.0)	**<.001**
Mean LDLc[g] (SD), mg/dL	94.1 (27.8)	87.6 (24.9)	**<.001**
Diabetes complications, n (%)			**<.001**
No complications	522 (44.6)	196 (16.7)	
Microvascular complications only[l]	477 (40.7)	678 (57.9)	
Macrovascular complications only[l]	46 (3.9)	27 (2.3)	
Micro- and macrovascular complications	115 (9.8)	257 (21.9)	
Missing	11 (0.9)	13 (1.1)	

[b]At baseline, 110 (9.4%) patients in DOC had missing data, while at follow-up, 61 (5.2%) patients in DOC. These missing data appeared when either no A1C levels (or unusual data) were recorded during the intake period or the A1C measures were not captured in Military Health System.

[c]At baseline, 1,100 (93.9%) patients in DOC had missing data, while at follow-up, 233 (19.9%) patients in DOC. These missing data appeared when either no SBP (or unusual data) were recorded during the intake period or the SBP measures were not captured in Military Health System.

[d]At baseline, 1,102 (94.1%) patients in DOC had missing data, while at follow-up, 263 (22.5%) patients in DOC. These missing data appeared when either no DBP (or unusual data) were recorded during the intake period or the DBP measures were not captured in Military Health System.

[e]At baseline, 149 (12.7%) patients in DOC, while at follow-up, 158 (13.5%) patients in DOC had missing data. These missing data appeared when either no total cholesterol levels (or unusual data) were recorded during the intake period or the total cholesterol measures were not captured in Military Health System.

[f]At baseline, 144 (12.3%) patients in DOC had missing data, while at follow-up, 162 (13.8%) patients in DOC had missing data. These missing data appeared when either no HDLc levels (or unusual data) were recorded during the intake period or the HDLc measures were not captured in Military Health System.

[g]At baseline, 174 (14.9%) patients in DOC had missing data, while at follow-up, 165 (14.1%) patients in DOC. These missing data appeared when either no LDLc levels (or unusual data) were recorded during the intake period or the LDLc measures were not captured in Military Health System.

[l]Microvascular complications included retinopathy, neuropathy, or nephropathy, while macrovascular complications included coronary heart disease (fatal or non-fatal myocardial infarction, sudden death, angina, ischemic heart disease, heart failure) or stroke (fatal or non-fatal stroke).

[m]P value was derived from paired t-test or McNemar's test for comparing non-missing data between baseline and follow-up in each group. The null hypothesis for insulin usage was that the proportion of patients using insulin after intervention is not different from that before intervention. The null hypothesis for diabetes complications was that the proportion of patients with any diabetes complications after intervention is not different from that before intervention.

Table 6. Changes in Medical Utilization of DOC Patients

Medical utilization	DOC (n=1,171)		
	Baseline	**Follow-up**	**P value[m]**
Mean yearly number of hospitalizations per patient[h] (SD)	1.6 (1.2)	1.5 (1.0)	.55
Mean yearly number of primary care visits per patient[i] (SD)	3.7 (2.9)	2.6 (2.5)	**<.001**
Mean yearly number of specialty care visits per patient[j] (SD)	10.5 (11.8)	11.9 (9.9)	**<.001**
Mean yearly number of dispensed medications per prescription per patient[k] (SD)	2.8 (1.2)	2.6 (1.1)	**<.001**
Mean yearly number of dispensed medications per patient[k] (SD)	16.7 (8.5)	16.0 (7.2)	**<.001**
Mean yearly number of A1C tests per patient[b] (SD)	2.4 (1.3)	2.6 (1.0)	**<.001**
Mean yearly number of lipid panel tests per patient[e] (SD)	2.0 (1.1)	2.1 (1.0)	.07

[b]At baseline, 110 (9.4%) patients in DOC had missing data, while at follow-up, 61 (5.2%) patients in DOC had missing data. These missing data appeared when either no A1C levels (or unusual data) were recorded during the intake period or the A1C measures were not captured in Military Health System.
[e]At baseline, 149 (12.7%) patients in DOC had missing data, while at follow-up, 158 (13.5%) patients in DOC had missing data. These missing data appeared when either no total cholesterol levels (or unusual data) were recorded during the intake period or the total cholesterol measures were not captured in Military Health System.
[h]At baseline, 988 (84.4%) patients in DOC had missing data, while at follow-up, 851 (72.7%) patients in DOC missing data. These missing data appeared when either no hospitalizations were recorded during the intake period or the hospitalization records were not captured in Military Health System.
[i]At baseline, 236 (20.2%) patients in DOC, while at follow-up, 900 (76.9%) patients in DOC had missing data. These missing data appeared when either no primary care visits were recorded during the intake period or the primary care visit records were not captured in Military Health System.
[j]At baseline, 26 (2.2%) patients in DOC while at follow-up, 14 (1.2%) patients in DOC had missing data. These missing data appeared when either no specialty care visits were recorded during the intake period or the specialty care visit records were not captured in Military Health System.
[k]At baseline, 4 (0.3%) patients in DOC had missing data, while at follow-up, 3 (0.3%) patients in DOC had missing data. These missing data appeared when either no medications were dispensed during the intake period or the dispensing records were not captured in Military Health System.
[m]P value was derived from paired t-test or McNemar's test for comparing non-missing data between baseline and follow-up in each group. The null hypothesis for insulin usage was that the proportion of patients using insulin after intervention is not different from that before intervention. The null hypothesis for diabetes complications was that the proportion of patients with any diabetes complications after intervention is not different from that before intervention.

Self-Management education

The numbers of patients who received DSME for each year at the DOC are as follows:

Table 7. Total Patients who Received DSME at the DOC

Year	Number of Patients
2006	434
2007	306
2008	403
Total	**1,143**

Clinical Information System

There have been a number of challenges in facilitating and integrating diabetes programs into military information technology systems

- The CDMP is currently undergoing a DIACAP review to integrate the Joslin Vision Network (JVN) and Notewriter programs. The DIACAP process for CDMP/JVN began in mid 2008. Since that time, UPMC staff has been working with SGR to move this process forward. It is unlikely that CDMP/JVN at WHMC will not be integrated until February 2010.
- CDMP is not intergraded into AHLTA. Currently healthcare providers must double enter clinical information.
- UPMC has chosen not to use an AADE system due to challenges, which were reported to AF/SGR. Flipside Media and Estenda Solutions are having ongoing conversations about possible collaboration in using their respective tools.

Summary

The DOC served as a team-based clinic where military beneficiaries with diabetes received care from an endocrinologist and a NP with the support of a dietitian, diabetes educator, ophthalmologist, and counselor. Both specialty and primary care was provided in a "one stop shop" approach to a capped enrollment of 1,200 patients. Patient benefits included: an established relationship/continuity of care with a consistent provider who was able to organize primary care while attending to the special needs of diabetes and on-site referral to a dietitian, educator, counselor and/or ophthalmologist.

Unsolicited patient satisfaction has been expressed and HbA1c levels improved. According to our findings, the DOC is a cost-effective model.

While the DOC influenced consistency in care services and improvement in glycemia, its full potential was unmet. The larger catchment area of the beneficiary population is reported to be >10,000 people. Services available to a subset of 1,200 cannot be justified. The DOC model also was limited in its availability to support care and services to smaller bases.

Access to appointments was also a problem for the DOC. Even though strategies like the implementation of the DIGMA approach were used, patients still had problems scheduling appointments in order to be seen in a reasonable timeframe. The provider's schedules filled quickly and wait time for appointments was approximately 3-4 months.

As a result of the aforementioned difficulties and the limited supply of diabetes specialists, the DCOE model was proposed and implemented. Unlike the DOC, the DCOE has the capability to serve 10,000 enrolled patients with diabetes. The DCOE also has a specialty focus and can provide in depth diabetes care/education and support for the following:

- Graduate Medical Education (GME) to WHMC interns/residents/fellows.
- Ongoing education to all WHMC professional staff, i.e. providing diabetes day in-service to Internal Medicine Department.

- DCOE "Go Teams" travel to Goodfellow AFB every month to conduct classes and patient visits. Future trips are planned in December, 2009 to Randolph (December 3), Laughlin (December 18) and to Navel Station Ingleside (December 16).
- Improved access where patients are seen on a timely basis.
- Care for complex management issues for patients referred by Primary Care Managers (PCM) for uncontrolled diabetes.

In the original plans for DCOE specialty services, patients were asked to be prepared and have the following information available for their specialty visit:

- Labs done prior to appointment, specifically HbA1c value
- Self-monitoring of blood glucose (SMBG) records

At its inception, the DCOE experienced a high clinic cancellation rate. The DCOE team re-examined the approach described above, recognizing that the patient cancellation rates may be a result of the DCOE admission criteria.
To remedy this situation, the DCOE leadership changed the DCOE entry criteria. Now if patients arrive without an HbA1c value, the LVN obtains a blood sample on site. The patient is then subsequently seen by the provider. If a patient comes to their appointment without SMBG records, the provider sees the patient and reiterates the importance of SMBG. Care and advice to the patient is provided, albeit limited without SMBG information. With these changes the patient visits and referrals have improved.

Figure 5 represents patient visits to DCOE providers, specifically NPs Pam Garwood and Bridget Slattery. The highlighted marker with an arrow represents the July date for which Ms. Slattery began seeing patients. We suspect the slight drop in the November numbers is likely due to the Thanksgiving holiday.

Figure 5. DCOE Patient Visits January-November 2009

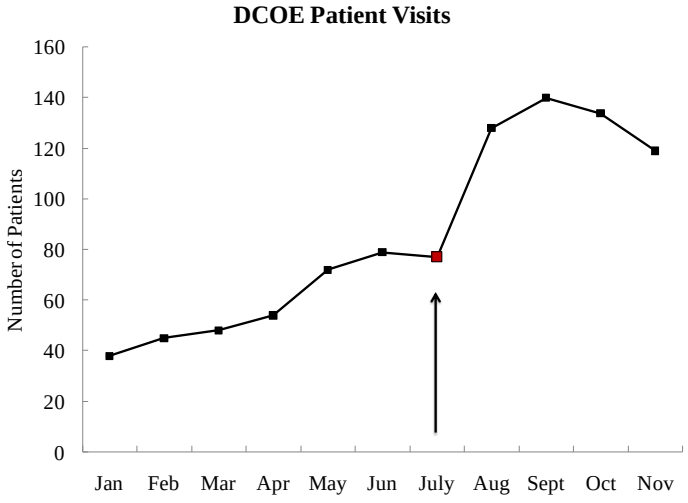
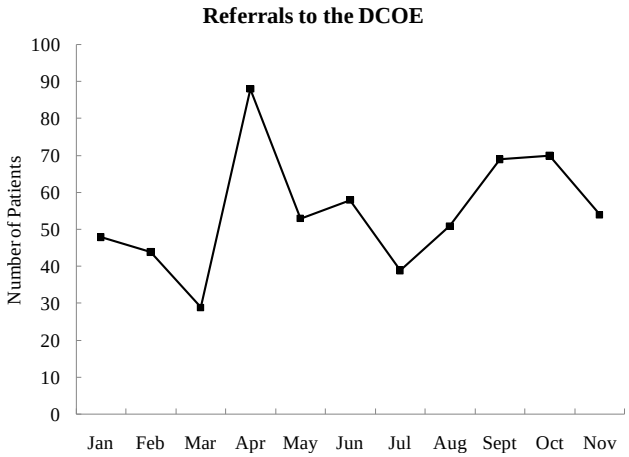


Figure 6. Patient Referrals to the DCOE January-November 2009



After remediation plans were put in place, patient referrals increased from March-November 2009 (Figure 6). We also noted an increase in referrals after a DCOE briefing to the Population Health Committee in March 2009. We attribute the slight drop in referrals during July to new resident turnover.

At the start of the DCOE operation, patient volume was low. This has been attributed to limited openings in provider schedules and newly hired nurse practitioners requiring additional time to be trained and oriented. These problems have been attended to by increasing the number of available appointments each provider has per day.

Since the patient's primary care has reverted back to the PCM, a new challenge has been reported. With the PCM workload of approximately 1200 per provider, ongoing consistent communication between the PCM and DCOE staff presents a challenge. Although information about the patient visit can be found in the patient chart, we identified a need to provide a second means of communication to the providers. The DCOE has established a dedicated email account so that the clinic providers can also email concerns to the PCM.

In interpreting findings, one needs to consider the potential influence of patient factors associated with a high-risk diabetes population on clinic processes and outcomes. For example, the DOC clinic provided care for a mix of patients, those who were adherent and non-adherent to management routines. The adherent DOC patients, in good to excellent glycemic control, could have influenced the positive mean HbA1c metrics. The DCOE model, however, where criteria for referral is HbA1c > 8.0%, is providing service to a more complex patient population. It has been reported that patients with uncontrolled diabetes experience a number of other problems that have an impact on care, like higher rates of recidivism and barriers to keeping appointments, etc [**15**]. Therefore interpreting process and patient outcomes must be interpreted with caution and careful consideration.

Figure 7. Aggregate HbA1c Levels for Patients at the DCOE January-November 2009

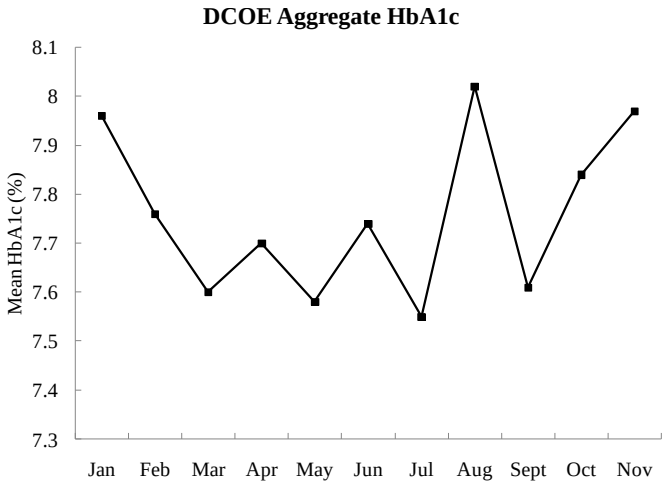


Figure 7 illustrates mean HbA1c values for DCOE patients collected through CDMP. CDMP only provides aggregate mean HbA1c values. Thus, this graph should be interpreted with caution. With aggregate mean values, both new referrals and follow up patient values are mixed.

In summary, we recommend the following:

- Monitoring and evaluating the DCOE and CCM models
- Recognition that integrating new health care delivery systems into large systems requires time and reassessment
- Explore opportunities for referrals, provider communications, schedule templates and criteria for enrollment
- Examining and testing opportunities for IT data systems
- Engaging high level leadership to support the new model of care delivery services
- Supporting Tricare initiative to include codes for reimbursement of DSME services

Objective 2. Cost-effectiveness of the CCM in a military population

Background

The CCM was implemented at WHMC in the DOC from January 2006 through December 2008. Our analysis aimed to estimate the costs, clinical outcomes, and cost-effectiveness of implementing the DOC based on "real-world" data from this military-based diabetes care program.

Methods

The DOC at WHMC

The DOC, in which the CCM methodology was applied, opened on January 3rd, 2006 and ended in December 2008. At that time, it was operating as a "one-stop-shop" for diabetes patients. All patients were seen for both diabetes treatment as well as their primary care in the DOC. The DOC had about 1,200 patients empanelled to them for care.

The population, who was defined as any individual with an ICD9 diagnosis of diabetes (250.XX) in the WHMC San Antonio area from January 2005 and December 2008, was included in the analysis. A total of 9,654 people with diabetes (1,171 DOC patients and 8,483 usual care [UC] patients) from Population Health database were identified, and their records between January 2005 and December 2008 were obtained, including demographics, clinical data (glycated hemoglobin, systolic/diastolic blood pressure, as well as blood glucose, total cholesterol, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol levels), medical utilization (hospitalizations, primary care visits, and specialty care visits), and pharmacy records. For DOC patients, we defined the records from 1 year prior to DOC entry as the pre-DOC data (or baseline), and all records after DOC entry as the post-DOC data (or follow-up); while for UC patients, we defined the records from 1 year prior to January 2006 (i.e., DOC starting date) as the pre-DOC data (or baseline), and all records after that time as the post-DOC data (or follow-up). Moreover, we only used data when patients were at age >=18 years by following the IRB policy. Hence, a total of 9,405 diabetics (97.4% of the original population; 9,405/9,654) were identified to be the final study cohort in this analysis, including 1,171 DOC patients and 8,234 UC patients. Table 1 below summarizes the demographic, clinical, and medical utilization characteristics at baseline and follow-up by two intervention strategies in these 9,405 diabetics.

The Framework of a Markov Decision Model

Using TreeAge Pro Suite 2009 (TreeAge Software, Williamstown, MA), we modified our prior Markov decision model [**43**] to estimate the incremental cost-effectiveness of the DOC compared to UC. The model directly incorporated intervention costs and effectiveness data from the DOC at WHMC to estimate life expectancy, quality-adjusted life-expectancy (expressed as quality-adjusted life-years, or QALYs), clinical outcomes (diabetes with chronic complications), as well as direct medical and nonmedical costs associated with the two intervention strategies (DOC vs. Usual Care (UC)). In the model, we used a base case from health care system perspective, which examined 50-year-olds with type 2 diabetes who participated in two intervention strategies in yearly cycles over a 20-year time horizon. Additionally, we assumed 100% intervention compliance.

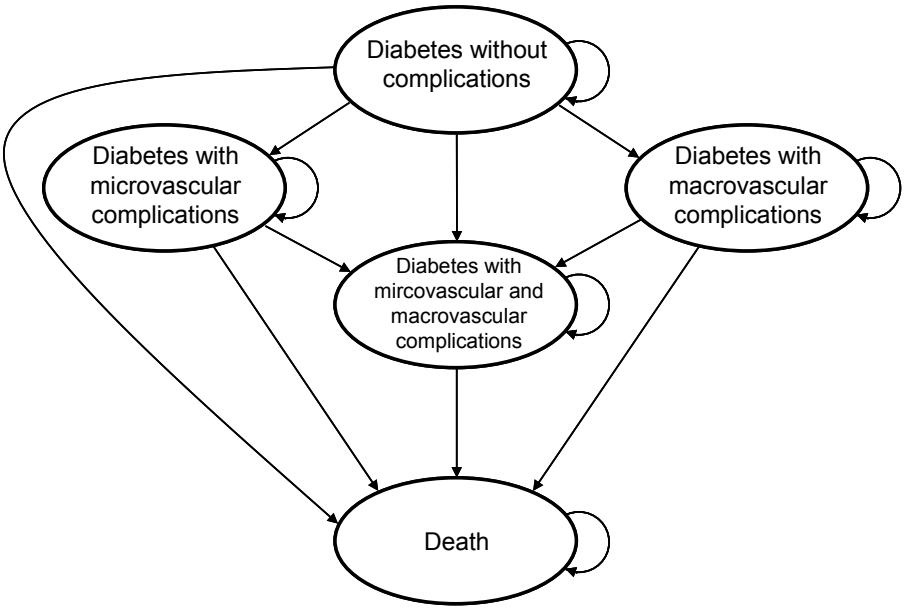
Basic Model Structure

The model is illustrated below in Figure 8, which describes the progression of disease through microvascular complications, macrovascular complications, and mortality. We assumed that all patients had uncomplicated diabetes at the start of the model. Over time, diabetes can progress to microvascular complications (including retinopathy, nephropathy, or neuropathy), macrovascular complications (including coronary heart disease or stroke), or both. We assumed that complications were irreversible and that patients in any health state could die in the next time period.

In the model, we aimed to evaluate the cost-effectiveness over next 20 years following the end of the intervention with the DOC strategy (the average intervention time: 2 years) and the UC strategy (the average intervention time: 3 years). We used the United Kingdom Prospective Diabetes Study (UKPDS) risk equations to predict long-term (over next 20 years) probabilities of developing micro- [**43-46**] and macrovascular [**47-49]**; http://www.dtu.ox.ac.uk/riskengine/] diabetes complications based on post-intervention demographic and clinical data in those diabetics who remained survived and without any diabetes complications at the study end. Hence, we identified, among all 9,405 diabetics, a total of 1,417 diabetics (196 DOC patients and 1,221 UC patients; See Table 8 below) who remained survived and without any diabetes complications at the study end. Table 9 below summarizes the demographic, clinical, and medical utilization characteristics at baseline and follow-up by two intervention strategies in these 1,417 diabetics, and Table 10 below summarizes the parameters applied in the UKPDS risk equations and the Markov decision model (See Figure 8 below) from the 1,417 and 9,405 diabetics respectively.

Figure 8. Markov-state diagram for the basic model structure.

Ovals indicate health states. Subjects may remain within a health state (short curved arrow) or may move to a different health state (straight arrow or long curved arrow).



Tables 8 and 9 represent our findings comparing patients in the DOC model to usual care (UC).

Table 8. Changes in demographic, clinical, and medical utilization characteristics by two intervention strategies in all 9,405 diabetics

Characteristic	DOC (n=1,171)		UC (n=8,234)		P value for baseline comparison[m]	Adjusted P value for follow-up comparison[n]
	Baseline	Follow-up	Baseline	Follow-up		
Demographic characteristics						
Mean age at study entry (SD), years	55.5 (9.2)	---	62.3 (14.3)	---	**<.001**	---
Gender, n (%)					.07	---
Female	516 (44.1)	---	3,864 (46.9)	---		
Male	655 (55.9)	---	4,370 (53.1)	---		
Race, n (%)					.50	---
White	370 (31.6)	---	1,399 (17.0)	---		
Non-White	193 (16.5)	---	780 (9.5)	---		
Missing	608 (51.9)	---	6,055 (73.5)	---		
Mean weight[a] (SD), kg	---	94.5 (21.8)	---	88.4 (21.5)	---	---
Mean height[a] (SD), cm	---	169.9 (10.9)	---	169.1 (10.7)	---	---
Mean BMI[a] (SD), kg/m^2	---	32.6 (6.3)	---	30.9 (6.7)	---	---
Insulin usage, n (%)					**.001**	.07
Yes	293 (25.0)	394 (33.6)	1,625 (19.7)	2,324 (28.2)		
No	874 (74.6)	774 (66.1)	6,124 (74.4)	5,667 (68.8)		
Missing	4 (0.3)	3 (0.3)	485 (5.9)	243 (3.0)		
Clinical characteristics						
Mean A1C[b] (SD), %	7.8 (1.6)	7.2 (1.2)	7.0 (1.4)	7.0 (1.3)	**<.001**	**<.001**
Mean SBP[c] (SD), mmHg	129.8 (18.5)	131.4 (14.9)	126.6 (12.8)	132.7 (15.3)	.18	**<.001**
Mean DBP[d] (SD), mmHg	79.4 (10.1)	77.4 (8.9)	78.4 (9.1)	75.2 (8.4)	.42	.41
Mean total cholesterol[e] (SD), mg/dL	176.0 (33.8)	164.4 (31.4)	170.1 (35.4)	165.7 (33.1)	**<.001**	**<.001**
Mean HDLc[f] (SD), mg/dL	48.9 (12.7)	47.9 (12.0)	49.7 (12.7)	49.5 (12.2)	.08	**.02**
Mean LDLc[g] (SD), mg/dL	94.1 (27.8)	87.6 (24.9)	89.0 (27.8)	86.4 (26.4)	**<.001**	**<.001**
Diabetes complications, n (%)					**<.001**	**<.001**
No complications	522 (44.6)	196 (16.7)	3,007 (36.5)	1,221 (14.8)		
Microvascular complications only[l]	477 (40.7)	678 (57.9)	2,656 (32.3)	3,165 (38.4)		
Macrovascular complications only[l]	46 (3.9)	27 (2.3)	656 (8.0)	302 (3.7)		
Micro- and macrovascular complications	115 (9.8)	257 (21.9)	1,605 (19.5)	3,391 (41.2)		
Missing	11 (0.9)	13 (1.1)	310 (3.8)	155 (1.9)		

Medical utilization characteristics						
Mean yearly number of hospitalizations per patient[h] (SD)	1.6 (1.2)	1.5 (1.0)	1.9 (1.7)	2.0 (1.6)	**<.001**	.12
Mean yearly number of primary care visits per patient[i] (SD)	3.7 (2.9)	2.6 (2.5)	4.2 (3.9)	3.9 (4.2)	**<.001**	**<.001**
Mean yearly number of specialty care visits per patient[j] (SD)	10.5 (11.8)	11.9 (9.9)	14.2 (15.0)	15.0 (14.9)	**<.001**	.06
Mean yearly number of dispensed medications per prescription per patient[k] (SD)	2.8 (1.2)	2.6 (1.1)	2.3 (1.0)	2.3 (0.9)	**<.001**	.09
Mean yearly number of dispensed medications per patient[k] (SD)	16.7 (8.5)	16.0 (7.2)	16.0 (9.1)	16.9 (8.5)	**.006**	**<.001**
Mean yearly number of A1C tests per patient[b] (SD)	2.4 (1.3)	2.6 (1.0)	2.1 (1.2)	1.9 (0.9)	**<.001**	**<.001**
Mean yearly number of lipid panel tests per patient[e] (SD)	2.0 (1.1)	2.1 (1.0)	1.7 (1.0)	1.5 (0.7)	**<.001**	**<.001**

Abbreviations: WHMC, Wilford Hall Medical Center; DOC, Diabetes Outreach Clinic; CEA, cost-effectiveness analysis; UC, usual care; SD, standard deviation; BMI, body mass index; A1C, glycated hemoglobin; SBP, systolic blood pressure; DBP, diastolic blood pressure; HDLc, high-density lipoprotein cholesterol; LDLc, low-density lipoprotein cholesterol.

[a]At follow-up, 19 (1.6%), 21 (1.8%), and 21 (1.8%) patients in DOC had missing data for weight, height, and BMI respectively, while 1,331 (16.2%), 1,334 (16.2%), and 1,340 (16.3%) patients in UC had missing data respectively. These missing data appeared when either no data (or unusual data) were recorded during the intake period or these measures were not captured in Military Health System.

[b]At baseline, 110 (9.4%) patients in DOC and 3,488 (42.4%) patients in UC had missing data, while at follow-up, 61 (5.2%) patients in DOC and 2,175 (26.4%) patients in UC had missing data. These missing data appeared when either no A1C levels (or unusual data) were recorded during the intake period or the A1C measures were not captured in Military Health System.

[c]At baseline, 1,100 (93.9%) patients in DOC and 7,918 (96.2%) patients in UC had missing data, while at follow-up, 233 (19.9%) patients in DOC and 3,492 (42.4%) patients in UC had missing data. These missing data appeared when either no SBP (or unusual data) were recorded during the intake period or the SBP measures were not captured in Military Health System.

[d]At baseline, 1,102 (94.1%) patients in DOC and 7,924 (96.2%) patients in UC had missing data, while at follow-up, 263 (22.5%) patients in DOC and 3,706 (45.0%) patients in UC had missing data. These missing data appeared when either no DBP (or unusual data) were recorded during the intake period or the DBP measures were not captured in Military Health System.

[e]At baseline, 149 (12.7%) patients in DOC and 4,826 (58.6%) patients in UC had missing data, while at follow-up, 158 (13.5%) patients in DOC and 4,557 (55.3%) patients in UC had missing data. These missing data appeared when either no total cholesterol levels (or unusual data) were recorded during the intake period or the total cholesterol measures were not captured in Military Health System.

[f]At baseline, 144 (12.3%) patients in DOC and 4,845 (58.8%) patients in UC had missing data, while at follow-up, 162 (13.8%) patients in DOC and 4,565 (55.4%) patients in UC had missing data. These missing data appeared when either no HDLc levels (or unusual data) were recorded during the intake period or the HDLc measures were not captured in Military Health System.

[g]At baseline, 174 (14.9%) patients in DOC and 4,878 (59.2%) patients in UC had missing data, while at follow-up, 165 (14.1%) patients in DOC and 4,574 (55.6%) patients in UC had missing data. These missing data appeared when either no LDLc levels (or unusual data) were recorded during the intake period or the LDLc measures were not captured in Military Health System.

[h]At baseline, 988 (84.4%) patients in DOC and 6,109 (74.2%) patients in UC had missing data, while at follow-up, 851 (72.7%) patients in DOC and 3,987 (48.4%) patients in UC had missing data. These missing data appeared when either no hospitalizations were recorded during the intake period or the hospitalization records were not captured in Military Health System.

[i]At baseline, 236 (20.2%) patients in DOC and 3,940 (47.9%) patients in UC had missing data, while at follow-up, 900 (76.9%) patients in DOC and 2,816 (34.2%) patients in UC had missing data. These missing data appeared when either no primary care visits were recorded during the intake period or the primary care visit records were not captured in Military Health System.

[j]At baseline, 26 (2.2%) patients in DOC and 798 (9.7%) patients in UC had missing data, while at follow-up, 14 (1.2%) patients in DOC and 263 (3.2%) patients in UC had missing data. These missing data appeared when either no specialty care visits were recorded during the intake period or the specialty care visit records were not captured in Military Health System.

[k]At baseline, 4 (0.3%) patients in DOC and 485 (5.9%) patients in UC had missing data, while at follow-up, 3 (0.3%) patients in DOC and 243 (3.0%) patients in UC had missing data. These missing data appeared when either no medications were dispensed during the intake period or the dispensing records were not captured in Military Health System.

[l]Microvascular complications included retinopathy, neuropathy, or nephropathy, while macrovascular complications included coronary heart disease (fatal or non-fatal myocardial infarction, sudden death, angina, ischemic heart disease, heart failure) or stroke (fatal or non-fatal stroke).

[m]P value was derived from two-sample t test or chi-square test for comparing non-missing data in 2 groups.

[n]P value was derived from multiple linear or logistic regression analysis for comparing non-missing data in 2 groups. Significant baseline demographic and clinical characteristics were adjusted in all analyses, while significant baseline medical utilization characteristics were only adjusted when analyzing each follow-up medical utilization characteri

Table 9. Changes in demographic, clinical, and medical utilization characteristics by two intervention strategies in the 1,417 patients surviving without diabetes complications at the study end

Characteristic	DOC (n=196)		UC (n=1,221)		P value for baseline comparison[l]	Adjusted P value for follow-up comparison[m]
	Baseline	Follow-up	Baseline	Follow-up		
Demographic characteristics						
Mean age at study entry (SD), years	51.1 (10.1)	---	47.3 (14.2)	---	**<.001**	---
Gender, n (%)					**.01**	---
Female	96 (49.0)	---	715 (58.6)	---		
Male	100 (51.0)	---	506 (41.4)	---		
Race, n (%)					.06	---
White	70 (35.7)	---	322 (26.4)	---		
Non-White	24 (12.2)	---	178 (14.6)	---		
Missing	102 (52.0)	---	721 (59.0)	---		
Mean weight[a] (SD), kg	---	90.0 (19.6)	---	88.6 (21.8)	---	---
Mean height[a] (SD), cm	---	169.1 (10.3)	---	167.7 (10.6)	---	---
Mean BMI[a] (SD), kg/m^2	---	31.4 (5.6)	---	31.4 (7.0)	---	---
Insulin usage, n (%)					.21	**.02**
Yes	28 (14.3)	37 (18.9)	113 (9.3)	220 (18.0)		
No	167 (85.2)	158 (80.6)	898 (73.6)	967 (79.2)		
Missing	1 (0.5)	1 (0.5)	210 (17.2)	34 (2.8)		
Clinical characteristics						
Mean A1C[b] (SD), %	7.8 (1.8)	7.2 (1.5)	6.8 (1.5)	7.0 (1.5)	**<.001**	**.004**
Mean SBP[c] (SD), mmHg	121.8 (14.2)	130.3 (15.3)	126.1 (12.8)	129.2 (13.4)	.11	.29
Mean DBP[d] (SD), mmHg	76.0 (9.5)	79.4 (9.5)	77.5 (8.7)	78.5 (7.7)	.42	.58
Mean total cholesterol[e] (SD), mg/dL	183.9 (32.2)	172.8 (30.6)	183.5 (34.3)	184.3 (33.2)	.92	**.002**
Mean HDLc[f] (SD), mg/dL	49.6 (13.3)	49.4 (12.6)	49.7 (11.6)	49.4 (11.6)	.94	.27
Mean LDLc[g] (SD), mg/dL	100.7 (28.3)	93.2 (25.8)	102.1 (27.6)	102.3 (27.7)	.61	**.002**
Medical utilization characteristics						
Mean yearly number of hospitalizations per patient[h] (SD)	1.5 (1.2)	1.3 (0.6)	1.5 (1.1)	1.3 (0.7)	.99	.95
Mean yearly number of primary care visits per patient[i] (SD)	3.1 (2.0)	2.0 (1.4)	3.5 (2.8)	3.0 (2.1)	**.04**	**.004**
Mean yearly number of specialty care visits per patient[j] (SD)	7.1 (9.1)	7.2 (4.8)	8.7 (11.1)	8.1 (9.0)	**.04**	.51

Mean yearly number of dispensed medications per prescription per patient[k] (SD)	2.6 (1.1)	2.6 (1.3)	2.1 (0.9)	2.2 (0.9)	**<.001**	.38
Mean yearly number of dispensed medications per patient[k] (SD)	13.6 (6.3)	12.1 (5.1)	10.5 (7.2)	11.1 (6.2)	**<.001**	.46
Mean yearly number of A1C tests per patient[b] (SD)	2.0 (1.1)	2.2 (0.9)	1.8 (1.1)	1.7 (0.8)	**.03**	**<.001**
Mean yearly number of lipid panel tests per patient[e] (SD)	1.9 (1.0)	1.7 (0.8)	1.7 (0.9)	1.4 (0.6)	**.04**	**<.001**

Abbreviations: WHMC, Wilford Hall Medical Center; DOC, Diabetes Outreach Clinic; CEA, cost-effectiveness analysis; UC, usual care; SD, standard deviation; BMI, body mass index; A1C, glycated hemoglobin; SBP, systolic blood pressure; DBP, diastolic blood pressure; HDLc, high-density lipoprotein cholesterol; LDLc, low-density lipoprotein cholesterol.

[a]At follow-up, 3 (1.5%) patients in DOC had missing data for weight, height, and BMI respectively, while 182 (14.9%), 180 (14.7%), and 182 (14.9%) patients in UC had missing data respectively. These missing data appeared when either no data (or unusual data) were recorded during the intake period or these measures were not captured in Military Health System.

[b]At baseline, 20 (10.2%) patients in DOC and 790 (64.7%) patients in UC had missing data, while at follow-up, 19 (9.7%) patients in DOC and 374 (30.6%) patients in UC had missing data. These missing data appeared when either no A1C levels (or unusual data) were recorded during the intake period or the A1C measures were not captured in Military Health System.

[c]At baseline, 169 (86.2%) patients in DOC and 1,064 (87.1%) patients in UC had missing data, while at follow-up, 54 (27.6%) patients in DOC and 471 (38.6%) patients in UC had missing data. These missing data appeared when either no SBP (or unusual data) were recorded during the intake period or the SBP measures were not captured in Military Health System.

[d]At baseline, 170 (86.7%) patients in DOC and 1,068 (87.5%) patients in UC had missing data, while at follow-up, 58 (29.6%) patients in DOC and 481 (39.4%) patients in UC had missing data. These missing data appeared when either no DBP (or unusual data) were recorded during the intake period or the DBP measures were not captured in Military Health System.

[e]At baseline, 28 (14.3%) patients in DOC and 955 (78.2%) patients in UC had missing data, while at follow-up, 41 (20.9%) patients in DOC and 865 (70.8%) patients in UC had missing data. These missing data appeared when either no total cholesterol levels (or unusual data) were recorded during the intake period or the total cholesterol measures were not captured in Military Health System.

[f]At baseline, 29 (14.8%) patients in DOC and 956 (78.3%) patients in UC had missing data, while at follow-up, 42 (21.4%) patients in DOC and 867 (71.0%) patients in UC had missing data. These missing data appeared when either no HDLc levels (or unusual data) were recorded during the intake period or the HDLc measures were not captured in Military Health System.

[g]At baseline, 34 (17.3%) patients in DOC and 958 (78.5%) patients in UC had missing data, while at follow-up, 41 (20.9%) patients in DOC and 872 (71.4%) patients in UC had missing data. These missing data appeared when either no LDLc levels (or unusual data) were recorded during the intake period or the LDLc measures were not captured in Military Health System.

[h]At baseline, 177 (90.3%) patients in DOC and 1,068 (87.5%) patients in UC had missing data, while at follow-up, 179 (91.3%) patients in DOC and 805 (65.9%) patients in UC had missing data. These missing data appeared when either no hospitalizations were recorded during the intake period or the hospitalization records were not captured in Military Health System.

[i]At baseline, 45 (23.0%) patients in DOC and 552 (45.2%) patients in UC had missing data, while at follow-up, 153 (78.1%) patients in DOC and 356 (29.2%) patients in UC had missing data. These missing data appeared when either no primary care visits were recorded during the intake period or the primary care visit records were not captured in Military Health System.

[j]At baseline, 7 (3.6%) patients in DOC and 321 (26.3%) patients in UC had missing data, while at follow-up, 1 (0.5%) patients in DOC and 27 (2.2%) patients in UC had missing data. These missing data appeared when either no specialty care visits were recorded during the intake period or the specialty care visit records were not captured in Military Health System.

[k]At baseline, 1 (0.5%) patients in DOC and 210 (17.2%) patients in UC had missing data, while at follow-up, 1 (0.5%) patients in DOC and 34 (2.8%) patients in UC had missing data. These missing data appeared when either no medications were dispensed during the intake period or the dispensing records were not captured in Military Health System.

[l]P value was derived from the two-sample t test or chi-square test for comparing non-missing data in 2 groups.

[m]P value was derived from multiple linear or logistic regression analysis for comparing non-missing data in 2 groups. Significant baseline demographic and clinical characteristics were adjusted in all analyses, while significant baseline medical utilization characteristics were only adjusted when analyzing each follow-up medical utilization characteristic.

Model input parameters are shown in Tables 10-20 below. Annual transition probabilities of death and of micro- or macro-vascular complications were predicted using the UKPDS risk equations and/or derived from the Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation (ADVANCE) study [**50**] (See Tables below).
Annual direct medical costs related to health care providers, laboratory tests, physician office visits, diabetic complications, death, and medications were included in the model (See Tables 15 and 16 below). We did not include indirect costs, assuming their capture in the assessment of QALYs, per the recommendation of the Panel on Cost-Effectiveness in Health and Medicine [**51**]. We used Medicare reimbursement data to estimate laboratory test costs (glycated hemoglobin and lipid panel) and physician office visits [**52**]. In addition, we used hourly wage costs for health care providers required by the DOC and UC based on National Occupational Employment and Wage Estimates [**53**]. We identified one-time and annual costs of diabetic complications, one-time costs of death, as well as medication costs for diabetes, hypertension, and cholesterol control, based on data from the models developed by the CDC and Research Triangle Institute International [**54**].

In analyses from the societal perspective, we included both direct medical and nonmedical costs. Direct nonmedical costs included patient time and monetary costs for physician office visits, and diabetes education classes/visits (See Table 15 below). Patient time costs for time missed from work or school to receive care and for time donated by others (e.g., for rides or babysitting) to allow care to occur were quantified based on the DOC data or published literature [**55**], then valued based on the average hourly wage of a US nonfarm production worker in 2000 [**53**] and the average annual numbers of visits/classes as derived from the DOC data. In addition, patient monetary costs including costs of parking or transportation and of babysitting or childcare were quantified based on data from the published literature [**55]**, then valued based on the average annual numbers of visits/classes as derived from the DOC data. We used the US Consumer Price Index [**56]** to convert all monetary costs to the US dollar rate for the year 2000.

Health utilities are a measure of health-related quality of life, with perfect health=1 and death=0. In a cost-effectiveness analysis, this utility weight for each health state is multiplied by time in that state. As an individual's health changes over time, these products are summed to represent the total number of QALYs [**51**]. To estimate health utilities associated with type 2 diabetes with or without complications, we applied an additive prediction model to estimate health utilities according to demographic, treatment, and complication variables [**57**]. The baseline health utility of 0.689 is the health utility for a non-obese man with T2D who is treated with diet and exercise, and who has no cardiovascular risk factors or microvascular, neuropathic, or cardiovascular complications. Table 17 below shows the health utilities used in the model.

Table 10. Parameters used in UKPDS risk equations and the Markov decision model

Parameter used in UKPDS risk equations (based on 1,417 diabetics surviving without diabetes complications at the study end)	**DOC (n=196)**	**UC (n=1,221)**
Adjusted mean A1C (%)[a]	6.8	7.1
Adjusted mean SBP (mmHg)[a]	128.4	130.2
Adjusted mean total cholesterol (mg/dL)[a]	173.7	185.0
Adjusted mean HDLc (mg/dL)[a]	49.6	48.2
Adjusted mean LDLc (mg/dL)[a]	94.7	104.0
Gender[a]	M: 100 (51.0%); F: 96 (49.0%)	M: 506 (41.4%); F: 715 (58.6%)
Age at study end (years)[b]	50	50
Race (White/Afro-Caribbean/Asian-Indian)[c]	Assumption	Assumption
Weight (kg)[d]	88.8	88.8
Height (cm)[d]	167.9	167.9
BMI (kg/m^2)[d]	31.4	31.4
Smoking status (Nonsmoker/Ex-smoker/Current Smoker)[e]	Assumption	Assumption
Creatinine clearance <100 ml/min (Yes/No)[f]	Assumption	Assumption
Atrial fibrillation (Yes/No)[g]	Assumption	Assumption
Macroalbuminuria (Yes/No)[h]	No	No
Microalbuminuria (Yes/No)[i]	No	No
Duration of diabetes[j]	Assumption	Assumption
Parameter used in the Markov decision model (based on all 9,405 diabetics)	**DOC (n=1,171)**	**UC (n=8,234)**
Diabetes complications at study end, n (%)		
No complications	196 (16.93)	1,221 (15.11)
Microvascular complications only	678 (58.55)	3,165 (39.18)
Macrovascular complications only	27 (2.33)	302 (3.74)
Micro- and macrovascular complications	257 (22.19)	3,391 (41.97)
Adjusted mean yearly number of primary care visits per patient (SE; 95% CI; median)[k]	2.7 (0.2; 2.3-3.1; 2.0)	3.9 (0.1; 3.7-4.1; 3.0)
Adjusted mean yearly number of specialty care visits per patient (SE; 95% CI; median)[k]	15.3 (0.4; 14.4-16.1; 9.0)	16.1 (0.3; 15.6-16.7; 10.3)
Adjusted mean yearly number of A1C tests per patient (SE; 95% CI)	2.6 (0.04; 2.58-2.72)	2.1 (0.02; 2.07-2.17)
Adjusted mean yearly number of lipid panel tests per patient (SE; 95% CI)	2.1 (0.03; 2.03-2.15)	1.6 (0.02; 1.55-1.63)

Abbreviations: UKPDS, United Kingdom Prospective Diabetes Study; DOC, Diabetes Outreach Clinic; UC, usual care; A1C, glycated hemoglobin; SBP, systolic blood pressure; HDLc, high-density lipoprotein cholesterol; LDLc, low-density lipoprotein cholesterol; M, male; F, female; BMI, body mass index.

[a]The mean value of each clinical data was adjusted for age at study entry and baseline A1C as well as accounted for half females and half males in each group.

[b]We used mean age at the study end from 1,417 patients.

[c]We assumed all is White for base case analysis.

[d]We used the most current post-study data (mean weight, height, and BMI) from 1,417 patients.

[e]We assumed all is non-smoker (since less than 10% of our population was the current smoker) for base case analysis.

[f]We assumed all is with creatinine clearance <100 ml/min for base case analysis.

[g]We assumed all is without atrial fibrillation (since no DOC patients had atrial fibrillation and only 15 (1.2%) UC patients had atrial fibrillation) for base case analysis.

[h]All is without macroalbuminuria for base case analysis.

[i]All is without microalbuminuria for base case analysis.

[j]We assumed the duration of diabetes for all patients is 5 years.

[k]We used the mean numbers for base case analysis

Table 11. Annual transition probability of developing CHD, stroke, nephropathy, neuropathy, and retinopathy in diabetes patients without any complications

Year	Fatal CHD		Nonfatal CHD		Fatal stroke		Nonfatal stroke		Nephropathy		Neuropathy		Retinopathy	
	DOC	UC	DOC	UC	DOC	UC	DOC	UC	DOC	UC	DOC	UC	DOC	UC
1	0.0013	0.0017	0.0029	0.0034	0.0001	0.0001	0.0009	0.0009	0.0135	0.0142	0.0350	0.0348	0.0555	0.0603
2	0.0015	0.0019	0.0030	0.0036	0.0001	0.0001	0.0010	0.0010	0.0152	0.0160	0.0515	0.0512	0.0624	0.0678
3	0.0017	0.0022	0.0031	0.0037	0.0001	0.0002	0.0011	0.0012	0.0163	0.0171	0.0601	0.0598	0.0668	0.0725
4	0.0020	0.0025	0.0032	0.0038	0.0002	0.0002	0.0013	0.0013	0.0171	0.0179	0.0665	0.0661	0.0701	0.0761
5	0.0023	0.0029	0.0033	0.0039	0.0002	0.0002	0.0015	0.0015	0.0177	0.0186	0.0715	0.0711	0.0727	0.0790
6	0.0026	0.0033	0.0034	0.0040	0.0002	0.0002	0.0017	0.0018	0.0183	0.0192	0.0757	0.0752	0.0750	0.0814
7	0.0029	0.0037	0.0035	0.0041	0.0002	0.0003	0.0019	0.0020	0.0188	0.0197	0.0793	0.0788	0.0769	0.0836
8	0.0033	0.0042	0.0036	0.0042	0.0003	0.0003	0.0022	0.0023	0.0192	0.0202	0.0824	0.0819	0.0787	0.0854
9	0.0038	0.0047	0.0037	0.0042	0.0003	0.0003	0.0025	0.0026	0.0196	0.0206	0.0852	0.0847	0.0802	0.0871
10	0.0042	0.0053	0.0037	0.0043	0.0004	0.0004	0.0029	0.0030	0.0199	0.0210	0.0877	0.0871	0.0817	0.0887
11	0.0048	0.0059	0.0038	0.0043	0.0004	0.0004	0.0033	0.0035	0.0203	0.0213	0.0899	0.0894	0.0830	0.0901
12	0.0053	0.0066	0.0038	0.0044	0.0005	0.0005	0.0038	0.0040	0.0206	0.0216	0.0920	0.0914	0.0842	0.0914
13	0.0060	0.0074	0.0038	0.0044	0.0005	0.0006	0.0043	0.0045	0.0208	0.0219	0.0938	0.0932	0.0853	0.0926
14	0.0066	0.0082	0.0038	0.0044	0.0006	0.0007	0.0049	0.0052	0.0211	0.0222	0.0955	0.0949	0.0864	0.0938
15	0.0074	0.0091	0.0038	0.0043	0.0007	0.0008	0.0056	0.0059	0.0214	0.0224	0.0970	0.0965	0.0874	0.0948
16	0.0082	0.0101	0.0038	0.0043	0.0008	0.0009	0.0065	0.0068	0.0216	0.0227	0.0984	0.0979	0.0883	0.0959
17	0.0090	0.0111	0.0038	0.0042	0.0009	0.0010	0.0074	0.0078	0.0218	0.0229	0.0998	0.0993	0.0892	0.0968
18	0.0100	0.0122	0.0037	0.0042	0.0010	0.0011	0.0084	0.0089	0.0220	0.0231	0.1010	0.1005	0.0900	0.0977
19	0.0110	0.0134	0.0037	0.0041	0.0011	0.0013	0.0096	0.0101	0.0222	0.0234	0.1021	0.1017	0.0909	0.0986
20	0.0120	0.0146	0.0036	0.0040	0.0013	0.0014	0.0110	0.0116	0.0224	0.0236	0.1031	0.1028	0.0916	0.0994

Abbreviations: CHD, coronary heart disease; DOC, Diabetes Outreach Clinic; UC, usual care.

Table 12. Annual transition probability of death and of developing macro- or microvascular complications in diabetes patients without any complications

Year	Death from any cause[a,b]		Development of macrovascular complications in patients staying live[a]		Development of microvascular complications with or without macrovascular complications[a]	
	DOC	UC	DOC	UC	DOC	UC
1	0.0022	0.0028	0.0038	0.0043	0.1010	0.1061
2	0.0025	0.0032	0.0040	0.0046	0.1244	0.1300
3	0.0029	0.0036	0.0042	0.0049	0.1375	0.1434
4	0.0033	0.0042	0.0045	0.0052	0.1472	0.1533
5	0.0038	0.0047	0.0048	0.0055	0.1549	0.1611
6	0.0043	0.0054	0.0051	0.0058	0.1613	0.1678
7	0.0049	0.0061	0.0055	0.0062	0.1669	0.1735
8	0.0055	0.0069	0.0058	0.0065	0.1718	0.1785
9	0.0063	0.0078	0.0062	0.0069	0.1762	0.1830
10	0.0071	0.0088	0.0066	0.0074	0.1802	0.1871
11	0.0079	0.0098	0.0071	0.0079	0.1838	0.1909
12	0.0089	0.0110	0.0076	0.0084	0.1872	0.1944
13	0.0100	0.0123	0.0082	0.0090	0.1903	0.1977
14	0.0111	0.0137	0.0088	0.0097	0.1932	0.2007
15	0.0124	0.0152	0.0096	0.0104	0.1959	0.2036
16	0.0138	0.0168	0.0104	0.0112	0.1985	0.2064
17	0.0152	0.0185	0.0113	0.0122	0.2010	0.2090
18	0.0169	0.0204	0.0123	0.0133	0.2034	0.2115
19	0.0186	0.0225	0.0135	0.0145	0.2056	0.2140
20	0.0205	0.0247	0.0149	0.0159	0.2078	0.2164

Abbreviations: DOC, Diabetes Outreach Clinic; UC, usual care.
[a]Microvascular complications included retinopathy, neuropathy, or nephropathy, while macrovascular complications included coronary heart disease or stroke. We assumed that (1) retinopathy, neuropathy, and nephropathy are independent but not mutually exclusive events, (2) coronary heart disease and stroke are independent but not mutually exclusive events, and (3) micro- and macrovascular complications are independent but not mutually exclusive events.
[b]We assumed that deaths from coronary heart disease or stroke account for 65% of all deaths in diabetes patients.

Table 13. Annual transition probability of disease progression in diabetes patients with microvascular complications only and those with macrovascular complications only

Parameter	Value		Reference
	Base case analysis	Probabilistic sensitivity analysis distribution[a]	
Annual probability of disease progression in DOC and UC patients with microvascular complications only			Zoungas et al. [30]
Development of macrovascular complications	0.1271	Beta (0.0330 to 0.2720)	
Annual probability of disease progression in DOC and UC patients with macrovascular complications only			Zoungas et al. [30]
Development of microvascular complications	0.0649	Beta (0.0182 to 0.1389)	

Abbreviations: DOC, Diabetes Outreach Clinic; UC, usual care.
[a]Beta (a to b)=beta distribution (95% CI).

Table 14. Annual death probability in diabetes patients with microvascular complications only, those with macrovascular complications only, and those with both complications

Year	Death from any cause in diabetes patients with microvascular complications only, those with macrovascular complications only, and those with both complications[a]	
	DOC	UC
1	0.0202	0.0208
2	0.0206	0.0212
3	0.0209	0.0217
4	0.0213	0.0222
5	0.0218	0.0228
6	0.0223	0.0234
7	0.0229	0.0241
8	0.0235	0.0249
9	0.0242	0.0258
10	0.0250	0.0267
11	0.0259	0.0278
12	0.0268	0.0289
13	0.0279	0.0301
14	0.0290	0.0315
15	0.0303	0.0330
16	0.0316	0.0346
17	0.0331	0.0363
18	0.0347	0.0382
19	0.0364	0.0402
20	0.0382	0.0423

Abbreviations: DOC, Diabetes Outreach Clinic; UC, usual care.
[a]The death probability for diabetes patients with complications was an additive probability by adding the constant risk of death to the age- and strategy-specific risk of death for diabetes patients without complications. The constant risk of death was based on medical literature (Zoungas et al. [57]), while the age- and strategy-specific risk of death for diabetes patients without complications was calculated using the United Kingdom Prospective Diabetes Study risk equations [47-49; http://www.dtu.ox.ac.uk/riskengine/].

Table 15. Cost parameters for the Markov decision model

Parameter	Value		Reference
	Base case analysis	Probabilistic sensitivity analysis distribution[a]	
Direct medical costs			
Annual health care provider costs per patient for diabetes education class and visit			DOC data; US Bureau of Labor Statistics [33]
Costs for GDC for the DOC and UC strategies, US$			
Endocrinologist	18	Uniform (9 to 27)	
Registered nurse/Certified diabetes educator	16	Uniform (13 to 19)	
Exercise physiologist	6	Uniform (3 to 9)	
Costs for DIGMA visit for the DOC strategy, US$			
Endocrinologist/Nurse practitioner	25	Uniform (13 to 38)	
Rotated staff	13	Uniform (11 to 16)	
Medical assistant	6	Uniform (5 to 7)	
Annual costs of laboratory tests and physicians office visits per patient			DOC data; CMS [32]
Costs for laboratory tests, US$			
Glycated hemoglobin			
DOC	37	Uniform (19 to 56)	
UC	30	Uniform (15 to 45)	
Lipid panel			
DOC	42	Uniform (21 to 63)	
UC	32	Uniform (16 to 48)	
Costs for physician office visits, US$			
Primary care			
DOC	162	Triangular (93 to 293)	
UC	238	Triangular (134 to 423)	
Specialty care			
DOC	817	Triangular (526 to 1,659)	
UC	907	Triangular (553 to 1,746)	
One-time and annual costs of complications per patient			Hoerger et al. [34]
One-time costs, US$			
No complications	0	Not varied	
Microvascular complications	1,710	Triangular (263 to 3,158)	
Macrovascular complications	2,932	Log normal (0 to 29,949)	
Microvascular and macrovascular complications	4,642	Log normal (263 to 33,107)	
Annual costs, US$			
No complications	0	Not varied	
Microvascular complications	4,947	Triangular (2,474 to 7,421)	
Macrovascular complications	1,199	Log normal (0 to 10,198)	
Microvascular and macrovascular complications	6,146	Log normal (2,474 to 17,619)	
One-time costs of death per patient			Hoerger et al. [34]
Age<65 years, US$	11,213	Not varied	

Age=65-74 years, US$	11,337	Not varied	
Direct nonmedical costs			
Annual time costs per patient			DOC data; US Bureau of Labor Statistics [33]; Smith et al. [35]
Costs for physician office visits, US$			
Primary care			
DOC	151	Not varied	
UC	218	Not varied	
Specialty care			
DOC	857	Not varied	
UC	902	Not varied	
Costs for GDC for the DOC and UC strategies, US$	56	Not varied	
Costs for DIGMA visit for the DOC strategy, US$	70	Not varied	
Annual monetary costs per patient			DOC data; US Bureau of Labor Statistics [33]; Smith et al. [35]
Costs for physician office visits, US$			
Primary care			
DOC	8	Not varied	
UC	12	Not varied	
Specialty care			
DOC	46	Not varied	
UC	48	Not varied	
Costs for GDC for the DOC and UC strategies, US$	12	Not varied	
Costs for DIGMA visit for the DOC strategy, US$	9	Not varied	

Abbreviations: DOC, Diabetes Outreach Clinic; GDC, Group Diabetes Class; DIGMA, Drop-In Group Medical Appointments; UC, usual care; CMS, Centers for Medicare and Medicaid Services.
[a]Uniform (a to b)=uniform distribution (minimum to maximum); Triangular (a to b)=triangular distribution (minimum to maximum); Log normal (a to b)=log normal distribution (95% CI).

Table 16. Medication costs of diabetes control, hypertension control, and cholesterol control for the Markov decision model

Medication cost (2000$)	Diabetes control		Hypertension control		Cholesterol control		Reference
	DOC	UC	DOC	UC	DOC	UC	
Year 1	148.47	34.65	547.33	163.63	1265.29	1265.29	Hoerger et al. [34]
Year 2	178.80	61.88	580.38	201.94	1265.29	1265.29	
Year 3	205.49	99.67	608.62	212.61	1265.29	1265.29	
Year 4	240.64	141.34	616.72	217.53	1265.29	1265.29	
Year 5	278.07	192.21	620.52	227.69	1265.29	1265.29	
Year 6	314.38	235.53	628.87	230.25	1265.29	1265.29	
Year 7	332.61	269.78	643.83	278.81	1265.29	1265.29	
Year 8	364.98	305.87	640.05	278.81	1265.29	1265.29	
Year 9	384.45	328.09	658.54	338.35	1265.29	1265.29	
Year 10	402.66	357.05	658.54	338.35	1265.29	1265.29	
Year 11	421.26	425.47	658.54	338.35	1265.29	1265.29	
Year 12	439.74	446.02	658.54	338.35	1265.29	1265.29	
Year 13	441.27	456.01	658.54	338.35	1265.29	1265.29	
Year 14	442.80	456.01	658.54	338.35	1265.29	1265.29	
Year 15 and up	445.85	456.01	658.54	338.35	1265.29	1265.29	

Abbreviations: DOC, Diabetes Outreach Clinic; UC, usual care.

Table 17. Parameters of health utilities and discount rates for the Markov decision model

Parameter	Value		Reference
	Base case analysis	Probabilistic sensitivity analysis distribution[a]	
Health utilities			Coffey et al. [37]
Diabetes without complications	0.689	Normal (0.662 to 0.716)	
Diabetes with microvascular complications	0.599	Uniform (0.519 to 0.678)	
Diabetes with macrovascular complications	0.631	Uniform (0.617 to 0.645)	
Diabetes with microvascular and macrovascular complications	0.599	Uniform (0.519 to 0.678)	
Discount rates			
Discount rate applied to costs, %	3.00	(2.00 to 5.00)[b]	Assumption
Discount rate applied to quality-adjusted life-expectancy, %	3.00	(2.00 to 5.00)[b]	Assumption

[a]Normal (a to b)=normal distribution (95% CI); Uniform (a to b)=uniform distribution (minimum to maximum).
[b](a to b)=(minimum to maximum). This parameter was not varied in the probabilistic sensitivity analysis.

Sensitivity Analyses

We first conducted one-way sensitivity analyses for model parameters (See Tables 13,15, and 17 above) to assess the effect of varying parameter estimates within clinically plausible ranges, identifying those parameters whose variation changed the base case incremental cost-effectiveness ratio (ICER) by more than ±10%. Second, we calculated the ICER of cost per QALY gained from societal perspective. Third, we tested the original assumption that all DOC and UC patients had uncomplicated diabetes at the start of the model by changing initial proportions of patients in 5 heath states (i.e., no complications, microvascular complications only, macrovascular complications only, both micro- and macrovascular complications, or death) at the start of the model to mirror the DOC cohort, and then to calculate the ICER of cost per QALY gained from societal perspective. Fourth, we again changed initial proportions of patients in 5 heath states at the start of the model to mirror the UC cohort, and then to calculate the ICER of cost per QALY gained from societal perspective.

We performed a probabilistic sensitivity analysis from health care system perspective, where model parameters were simultaneously varied over distributions [**58**]. Distributions for parameters were chosen based on the level of certainty and the characteristics of the parameter range: beta distribution was assigned for probabilities; uniform, triangular, or log normal distributions were assigned for costs; and normal or uniform distributions were chosen for utilities. A value from each parameter's probability distribution was randomly selected during each of 10,000 Monte Carlo iterations, and then these values were used to compute strategy cost-effectiveness for each iteration. We used the cost-effectiveness acceptability curve [**59**] to summarize probabilistic sensitivity analysis results, showing the likelihood that a given strategy would be favored for a given willingness-to-pay threshold [**60**]. A willingness-to-pay (or acceptability) threshold is the maximum amount that society is willing to pay for an incremental gain in health [**60**]. Although there is no absolute threshold, Braithwaite and colleagues [**61**] argue that a plausible range of society's willingness-to-pay for incremental cost-effectiveness of modern health care may be $100,000 per QALY gained or more

Results

Base Case Analysis

From health care system perspective, Table 18 below summarizes the ICERs of cost per complication or death avoided at the 3-, 5-, or 10-year time horizon of model between the DOC and UC, and Figure 2 below shows the trend of the ICERs (cost per complication or death avoided) over the 20-year time horizon of model. Before the 10-year time horizon of model, the DOC compared to UC cost less than $141,000 per complication or death avoided, while at the 20-year time horizon of model, the DOC cost about $1,050,000 per complication or death avoided. In addition, Table 12 below summarizes the results of cost-effectiveness analysis based on health care system perspective for the DOC and UC over a 20-year time horizon of model.

Compared to UC, the DOC cost $4,017 more and produced a gain of 0.104 QALYs, resulting in an ICER of $38,617 per QALY gained. In comparison with Tables 18 and 19, and Figure 9 below, the ICERs of cost per complication or death avoided increased dramatically due to more deaths in the UC and relatively more total transitions out of uncomplicated patients in the DOC over time. Hence, evaluation of cost per complication or death avoided by following cohorts for longer periods of time would dilute the true impact of the DOC intervention, while analysis of cost per QALY gained would be the truer summary measure of the DOC intervention, which is not diluted by mortality over time.

Sensitivity Analyses

First, Figure10 below shows the results of one-way sensitivity analyses for parameters whose variations changed the base case ICER ($38,617 per QALY gained) by more than ±10%. Six sensitive parameters were identified, including yearly cost for specialty care visits (UC and DOC), yearly probability of developing macrovascular complications in those patients with microcomplications already (UC and DOC), and yearly cost for primary care visits (UC and DOC). Second, from societal perspective, the DOC compared to UC cost $3,671 more and produced a gain of 0.104 QALYs, resulting in an ICER of $35,298 per QALY gained over a 20-year time horizon of model (See Scenario 1 in Table 20 below). Third, we changed initial proportion of cohorts in 5 health states at the start of the model based on the likelihood of having complications in DOC patients (i.e., no complications: 16.93%; microvascular complications only: 58.55%; macrovascular complications only: 2.33%; both complications: 22.19%; and death: 0%; See Table 8 above) and we found that the DOC compared to UC cost $4,126 more and produced a gain of 0.075 QALYs, resulting in an ICER of $55,097 per QALY gained from societal perspective (See Scenario 2 in Table 20 below). Fourth, we again changed initial proportion of cohorts in 5 health states at the start of the model based on the likelihood of having complications in UC patients (i.e., no complications: 15.11%; microvascular complications only: 39.18%; macrovascular complications only: 3.74%; both complications: 41.97%; and death: 0%; See Table 8 above) and we found that the DOC compared to UC cost $4,137 more and produced a gain of 0.074 QALYs, resulting in an ICER of $55,692 per QALY gained from societal perspective (See Scenario 3 in Table 20 below).

When parameters were simultaneously varied over their corresponding probability distributions in the probabilistic sensitivity analysis (See Figure18 below), the UC was more likely to be favored if a willingness-to-pay (WTP) threshold was less than $41,000 per QALY gained, while the DOC was favored given the WTP more than that. In addition, using a WTP of $50,000 per QALY gained, the DOC was favored in 56% of model iterations, while using a WTP of $100,000 per QALY gained, the DOC was favored in 89% of model iterations.

Tables and Figures below represent information relevant to cost evaluation.

Table 18. Results of cost per complication or death avoided at the 3-, 5-, or 10-year time horizon of model

Time horizon	Strategy	Cost (US$)	Incremental cost (US$)	Effectiveness[a]	Incremental effectiveness[a]	ICER (Cost per complication or death avoided)
3	UC	$8,658	-	76.62%	-	-
	DOC	$9,458	$800	77.74%	1.12%	$71,411
5	UC	$17,285	-	54.58%	-	-
	DOC	$18,639	$1,354	56.33%	1.75%	$77,354
10	UC	$42,887	-	19.87%	-	-
	DOC	$45,237	$2,350	21.54%	1.67%	$140,674

Abbreviations: DOC, Diabetes Outreach Clinic; UC, usual care; ICER, incremental cost-effectiveness ratio.
[a]Effectiveness and incremental effectiveness depicted probability of avoiding complications or death.

Table 19. Results of cost per quality-adjusted life-year gained over a 20-year time horizon of model

Strategy	Cost (US$)	Incremental cost (US$)	Effectiveness (QALYs)	Incremental effectiveness (QALYs)	ICER (Cost per QALY gained)
UC	$87,704	-	8.576	-	-
DOC	$91,720	$4,017	8.680	0.104	$38,617

Abbreviations：DOC, Diabetes Outreach Clinic; UC, usual care; QALYs, quality-adjusted life-years; ICER, incremental cost-effectiveness ratio.

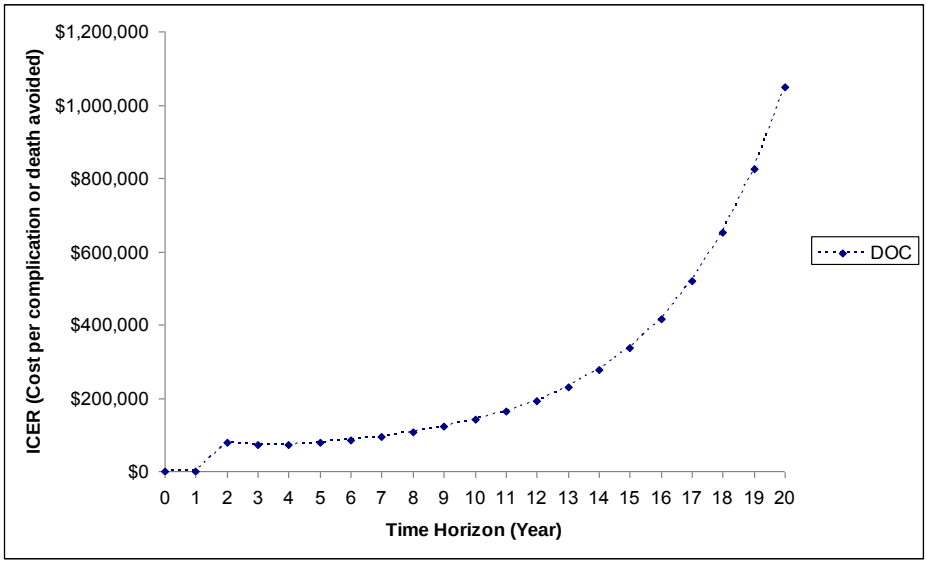
Table 20. Results of one-way sensitivity analyses for three scenarios over a 20-year time horizon of model

Scenario	Strategy	Cost (US$)	Incremental cost (US$)	Effectiveness (QALYs)	Incremental effectiveness (QALYs)	ICER(Cost per QALY gained)
1[a]	UC	$104,481	-	8.576	-	-
	DOC	$108,152	$3,671	8.680	0.104	$35,298
2[b]	UC	$122,032	-	7.433	-	-
	DOC	$126,158	$4,126	7.508	0.075	$55,097
3[c]	UC	$122,694	-	7.411	-	-
	DOC	$126,831	$4,137	7.486	0.074	$55,692

Abbreviations: DOC, Diabetes Outreach Clinic; UC, usual care; QALYs, quality-adjusted life-years; ICER, incremental cost-effectiveness ratio.
[a]Scenario 1: We calculated the ICER of cost per QALY gained from societal perspective.
[b]Scenario 2: We changed initial proportions of patients in 5 heath states at the start of the model to mirror the DOC cohort, and then to calculate the ICER of cost per QALY gained from societal perspective.
[c]Scenario 3: We changed initial proportions of patients in 5 heath states at the start of the model to mirror the UC cohort, and then to calculate the ICER of cost per QALY gained from societal perspective.

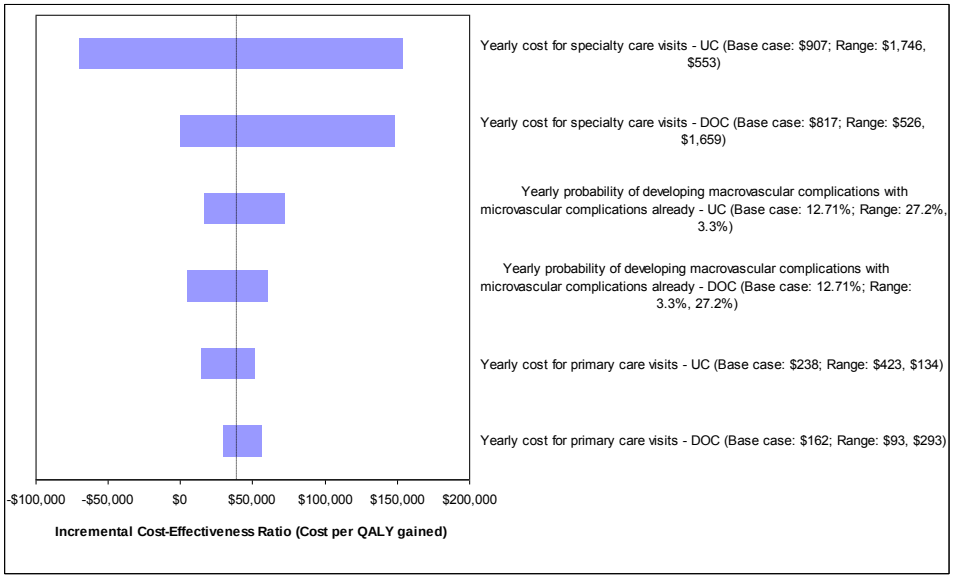
Cost per diabetes complication or death avoided by the model time horizon is illustrated in Figure 9.

Figure 9. Cost per complication or death avoided by the model time horizon for the Diabetes Outreach Clinic (DOC) compared to the Usual Care strategy. ICER=incremental cost-effectiveness ratio.



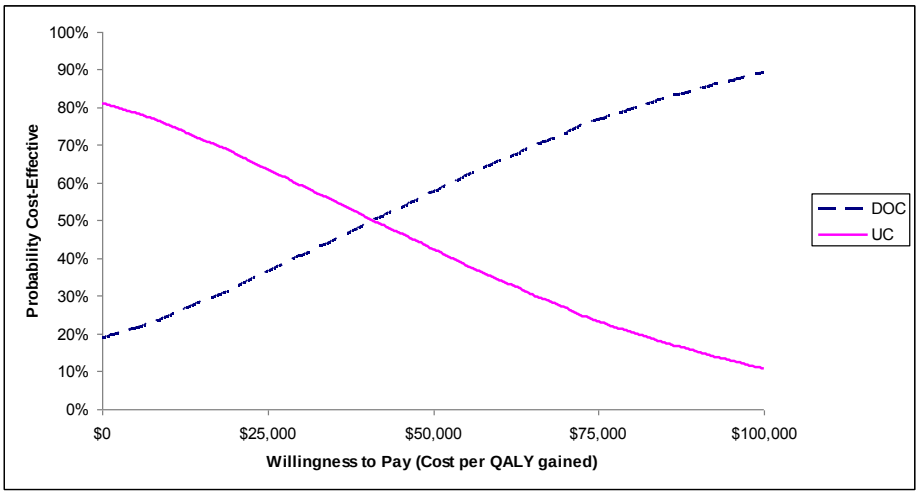
One-way sensitivity analyses of parameters whose variations changed the incremental cost-effectiveness ratio (x-axis) by more than ±10%. Horizontal bars depicted the range of incremental cost-effectiveness ratios corresponding to the values shown in each parameter. The vertical dotted line depicted the base case incremental cost-effectiveness ratio ($38,617 per QALY gained). QALY=quality-adjusted life-year.

Figure 10. One-way sensitivity analyses for the Diabetes Outreach Clinic (DOC) and Usual Care (UC) strategy.



The acceptability curve depicts the likelihood of the DOC or UC strategy being favored for a given cost-effective threshold (willingness-to-pay). QALY=quality-adjusted life-year. In a cost-effectiveness analysis, the health utility weight (i.e., perfect health=1; death=0) for each health state is multiplied by time (life-years) in that state. As an individual's health changes over time, these products are summed to represent the total number of quality-adjusted life-expectancy (expressed in quality-adjusted life-years, or QALYs). For example, an individual with perfect health (health utility=1) for 20 years has 20 QALYs, while an individual with uncomplicated diabetes (health utility=0.689; See Table 10 above) for 20 years has 13.78 QALYs.

Figure 11. Probabilistic (second-order Monte Carlo) sensitivity analysis for the Diabetes Outreach Clinic (DOC) and Usual Care (UC) strategy.



Summary

- From health care system perspective, the cost per complication or death avoided for the DOC compared to UC at 3 years ($71,411 per complication or death avoided), 5 years ($77,354 per complication or death avoided), and 10 years ($140,674 per complication or death avoided) was not unreasonable economically.
- From health care system perspective, the DOC compared to UC had reasonable expenditures associated with gaining QALYs over a 20-year time horizon of model ($38,617 per QALY gained).
- From societal perspective, the DOC compared to UC also had reasonable expenditures associated with gaining QALYs over a 20-year time horizon of model ($35,298 per QALY gained).
- The DOC performed with the CCM methodologies in the military-based setting should be a promising investment.
- Caveats/Limitations:
    - Interpretations of study results are contingent on data quality and model assumptions.
    - Subjects in this analysis were representative of the population with diabetes in a military community, but may not be fully generalizable to other populations or health care settings.
    - Evaluation of cost per complication or death avoided by following cohorts for longer periods of time would dilute the true impact of the DOC intervention, while analysis of cost per QALY gained would be the truer summary measure of the DOC intervention, which is not diluted by mortality over time.

Objective 3. Effectiveness of a technology-based educational program at WHMC

Background

DSME is considered to be an important part of clinical care ([**62**]. Goals set for Healthy People 2010 are to increase those reached with diabetes education from 40% (1998) to 60% (2010) [**63**]. Although the benefits of DSME have been widely accepted, participation rates are disappointing in that only one-third to one-half of U.S. patients with diabetes receive DSME [**64, 65**].

The numbers of patients who receive DSME are disappointingly small. Access to education has been proposed as a barrier. It has been reported that there are only 14,000 certified diabetes educators in the U.S. With the growing numbers of diabetes patients, efforts to expand the reach of educators are critical.

We explored the use of the DVD program for the military setting to help increase awareness for the DSME and encourage patients to attend.

Our objectives were to:

- Implement diabetes education tools and management tools for diabetes educators to effectively and efficiently deliver and monitor diabetes education.
- Compare user satisfaction of technology based education program/tool to standard practice at WHMC

Methods

We completed the following:

- Developed primary content that consists of video, animation, and text on Diabetes Self Care Behaviors
- Gained feedback to refine content and format of technology based education program/tool
- Disseminated technology based education program/tool for patient use at home
- Assessed educator satisfaction on technology based education program/tool to standard practice education

Development of the DVD Tool

A 50-minute DSME video was developed in DVD format. Diabetes educators at UPMC, PRIDE and WHMC, all of whom have expertise in the field, reviewed, validated and refined the content of the video scripts. A representative from the National Diabetes Education Program (NDEP) also reviewed the script and provided input.

DVD Tool

The DVD provides patients with basic diabetes survival skills to help manage their diabetes until they can be seen for outpatient DSME. The DVD was designed to engage and empower patients to take on a greater role in their own self-management and encourages them to attend DSME. This message is consistently reinforced through both copy delivered by the actors and visuals incorporated into the video.

The DVD is organized into chapters, each delivered by actors of varying genders, ages and ethnicities and employs the use of sound and graphical animation. Chapters include:

- What is Diabetes?
- Eating & Activity
- Medication
- Blood Glucose Monitoring
- Giving Yourself Insulin
- Low/High Blood Glucose
- Sick Day Management
- Coping with Diabetes
- Finding Support
- Your Next (Doctor) Appointment

Packaging

The DVD packaging, which also includes a business card and a patient satisfaction survey, is designed to be engaging and user-friendly. Through the use of a simple 3-step process, the patient is encouraged to 1) watch the DVD, 2) call the number on the attached business card to connect to an educator who will enroll them in education and 3) send back a patient satisfaction survey regarding the helpfulness of the DVD.

Support Person Brochure

A support person brochure is also included in the packaging. The brochure is targeted to a member of the patient's support team, e.g. a spouse, sibling, caregiver, etc. The brochure explains to the support person the importance of watching the video with the patient so that they can provide assistance and support.

Distribution (Settings)

Inpatient Units

The DVDs were distributed by staff nurses in inpatient units. The DVDs were given to patients before being discharged from the hospital to provide survival skills for safe transition at home and encourage them to attend DSME. The WHMC inpatient units include:

- General Surgery Unit
- Cardiac Unit
- General Medical Unit
- Hematology-Oncology (Hem-Oc) Unit

Outpatient Clinic Locations

The DVDs were also distributed through several outpatient clinic locations. Distribution methods for the outpatient clinics were determined by WHMC to meet the needs and operating structure of the individual outpatient clinic locations. The DVDs were used at DCOE, the Internal Medicine Clinic and Kelly Family Clinic to encourage patients to attend DSME at DCOE. The DVDs were used at Goodfellow Family Clinic to encourage patients to attend DSME at Goodfellow Family Clinic.

Data Collection

Monthly Reporting Form

Nina Watson (ret. Lt. Col.) completed a monthly reporting form.

Educator Satisfaction Survey

To determine diabetes educator satisfaction, a survey was administered to all of the diabetes educators involved in the project. They were asked to answer "yes" or "no" to the following questions:

5. **Did you find the DVD to be useful in preparing patients for DSME?**

This question was asked to determine if the content was found to be useful in providing patients with the survival skills.

6. **Do you think this DVD extends your reach and helps drive patients to DSME?**

The DVD serves to extend the reach of the diabetes educator.

7. **Traditionally, standard practice of diabetes education has been communicated to be participation in a didactic class. Do you think this DVD communicates the importance of patient participation/engagement in a diabetes self-management education program?**

We wanted to learn if a technology-based education tool is effective in conveying the importance and increasing awareness for patient participation in DSME. The DVD was designed to engage and empower the patient to take on a greater role in their own self-management.

8. **Would you recommend this DVD to a colleague?**

It has been shown that there is a strong correlation between product loyalty and answering the question "Would you recommend this product to a friend or colleague?"

Patient Satisfaction Survey

In an effort to determine patient satisfaction with the DVD program, a survey was developed and included in the DVD packaging. The questions in the patient satisfaction survey are as follows:

1. **"How helpful was the video in giving you a better understanding of how to care for your diabetes?"** ("not at all helpful", "somewhat helpful", or "very helpful")
2. **"What section of the video was most helpful to you?"** (open-ended response)
3. **"Is there anything else that you wish was included in the video?"** (open-ended response)
4. **"After watching the video, how confident do you feel in caring for your diabetes?"** ("not at all confident", "somewhat confident", or "very confident")
5. **"Would you refer this video to a friend with diabetes?"** ("yes" or "no")
6. **"The video emphasized the importance of enrolling in the Diabetes Self-Management Education class. Have you gotten the referral from your doctor and registered for the class yet?"** ("yes" or "no")

- "If no, do you plan to register for the class?"
- "If no, please explain why"

Analysis

This project did not require IRB approval. A WHMC Human Research Protection Quality Assurance/Improvement Checklist was approved. The Nursing Standards and Practice Working Group was briefed on the DVD program on May 29, 2009.

The number of DVDs distributed at each location during the designated time frame was counted.

Results

DVD Distribution

From August 1, 2009 through November 15, 2009, a total of 1,266 DVDs were disseminated through inpatient units and outpatient clinic locations, 365 and 901 respectively.

Inpatient Units				
	Aug	Sep	Oct	Nov
General Surgery	23	33	19	7
Cardiac	27	31	22	9
General Medical	36	43	27	17
Hem-Onc	17	26	19	9

Outpatient Clinic				
	Aug	Sep	Oct	Nov
DCOE	58	147	126	73
Internal Medicine	94	76	63	12
Kelly Family	31	48	51	22
Goodfellow Family	18	19	14	49

Educator Satisfaction Survey

Satisfaction surveys were returned by all of the diabetes educators from WHMC. All of the educators reported high satisfaction with the DVD tool. In summary, the diabetes educators reported that:

- The content was useful in providing patients with the survival skills needed to manage their diabetes at home until they could be seen for outpatient DSME.
- The DVD helped extend the reach of the educator and encouraged patients to attend DSME.
- A technology based education program is effective in conveying the importance and increasing the awareness for patient participation in diabetes education.
- They would recommend the DVD to a friend, therefore showing a strong degree of satisfaction for the DVD.

Patient Satisfaction Survey

The patient satisfaction survey was included in the DVD packaging. The return rate was low, thus we determined that due to the low response we would not be able to draw relevant conclusions from the patient surveys. Of those that were returned, the patients favorably reported that:

- The video was “somewhat helpful” or “very helpful” in giving them a better understanding of how to care for their diabetes.
- They felt “very confident” in caring for their diabetes after watching the video.
- They would refer the video to a friend with diabetes.
- They have already sought out a referral from their physician to attend the DSME class or plan on seeking out a referral and attending the DSME class.
- The content of the video was very helpful. Specific sections noted included coping with diabetes, glucose monitoring and eating habits.

Summary

1,266 DVDs were distributed through inpatient units and outpatient clinic locations within a three month period. Educators reported high satisfaction with the program in that the DVD helped to extend their reach, helped to prepare patients for DSME and increased awareness for patient participation in DSME. We were disappointed in the low rate of return for the patient satisfaction survey. However we appreciate that return rates on questionnaires are usually low unless linked to an incentive.

INPATIENT GLYCEMIC MANAGEMENT

Although national attention has been given to improving glycemic control for hospitalized patients, it has remained a challenging goal for many health centers. Many of the steps needed to improve the management of inpatients with hyperglycemia (or hypoglycemia) involve changes to long standing practice patterns, process of care and work flow habits. Competing priorities, staffing shortages and changes, and limited resources can also present obstacles that prevent the transition of glycemic control guidelines into the daily routine of hospital care. Without safe and proven treatment strategies for glycemic control, however, patients with poor glycemic management are at risk for further health complications.

Adopting and implementing hospital-wide policies and standardized order sets help to guide healthcare providers in selecting the appropriate regimen while avoiding adverse events [**1**]. In an effort to improve the quality of inpatient care, the University of Pittsburgh Medical Center (UPMC) developed, evaluated, and successfully implemented a series of inpatient glycemic management protocols throughout the UPMC hospital system [**2**].

Military Populations

UPMC, through its partnership with the United States Air Force (USAF), has implemented selected glycemic management protocols at Wilford Hall Medical Center (WHMC).

An interdisciplinary UPMC Glycemic Management and investigative team worked to implement and evaluate inpatient glycemic management protocols in WHMC inpatient units. The Glycemic Management Team also provides inpatient staff with education and support as new management protocols are introduced to inpatient units.

In implementing glycemic management protocols at WHMC, UPMC has addressed the following objectives:

1. Document plan for implementation of glycemic management protocols
2. Implement inpatient glycemic management protocols at WHMC
3. Implement a data management system for inpatient glycemic management protocols
4. Report on the effectiveness and/or outcomes of inpatient glycemic management protocols

Objective 1. <u>Document plan for implementation of glycemic management protocols</u>

Below is the list of selected inpatient glycemic management protocols. Protocols are to be implemented in a series by the Glycemic Management Team.

Pre-Series 1

The Insulin Infusion Protocol (IIP) was implemented in WHMC inpatient units and wards in September 2007, before Series 1 protocols were implemented.

Insulin Infusion Protocol (IIP

Series 1

These protocols are currently being implemented in WHMC inpatient units and wards. Education and training for protocols is ongoing. Implementation began at the end of September 2009 after obtaining required approvals. Delays for implementation of these protocols have been reported to AF/SGR.

Transition from Intravenous to Subcutaneous Insulin Protocol
Standardized Physician Order Sets for Subcutaneous Insulin
Diabetic Ketoacidosis Protocol/ Hyperglycemic Hyperosmolar State (DKA/HHS)
Hypoglycemia Protocol (implemented on FY07 award)

Series 2

A teleconference with Dr. Korytkowski (UPMC North) was conducted on November 4, 2009 to discuss the insulin pump protocol. Exploration of the implementation of other protocols is underway.

Insulin Pump Protocol
Inpatient Diabetes Education Protocol
Discharge Instructions Protocol

Series 3

The following Series 3 protocols require the engagement of WHMC surgical staff. Currently, the Glycemic Management Team is building relationships with inpatient surgical staff.

Glycemic Management of Patients on High Dose Steroids Protocol
Anesthesia Management Protocol

Objective 2. Implementation of inpatient glycemic management protocols at WHMC

Prior to implementing the following protocols, Quality Assessment (QA) approval was received from WHMC Institutional Review Board (IRB). Approval to implement protocols was also received from the appropriate forms committee and inpatient safety committee at WHMC.

Transition from Intravenous to Subcutaneous Insulin Protocol
Standardized Physician Order Set of Subcutaneous Protocol
DK)/ HHS Protocol
Hypoglycemia Protocol (FY07 funding)

Data collection related to these protocols has commenced. Spreadsheets used for data collection have been revised for use in any of the additional inpatient units where protocols are to be implemented.

As agreed with AF/SGR, this report is limited to data for the Insulin Infusion Protocol (IIP) in Series 1 protocols. UPMC will continue to collect data and report on protocols currently being implemented in Series 1.

Objective 3. Implementation of a data management system for inpatient glycemic management protocols

As of September 2009, the Glycemic Management Team has been able to access both RALS-TCGM and RALS-PLUS systems. Therefore, data collection related to the IIP and Series 1 protocols has been less of a challenge, as previously reported to AF/SGR.

Objective 4. Report on effectiveness and/or outcomes of inpatient glycemic management protocols

Background

Hyperglycemia is associated with increased morbidity and mortality in various populations of critically ill patients [**3**-**10**]. Epidemiologic data, and uncontrolled observational data, have for many years associated acute and chronic hyperglycemia with adverse inpatient outcomes [**1**]. Several intervention studies have linked reversal of hyperglycemia to better clinical outcomes in medical and surgical patients [**1, 11**-**13**]. However, recent data in critically ill patients suggest that aggressive management of hyperglycemia is not always associated with improved outcomes and may be associated with some risks. These findings have led to more conservative treatment recommendations [**1**, **13**].

Critically ill hospitalized patients are prone to large variances in blood glucose (BG) concentrations due to a variety of metabolic changes related to stress. Stress resulting from surgery, trauma, or sepsis causes an increased secretion of stress hormones such as cortisol and catecholamines. As a consequence, hyperglycemia and insulin resistance occurs even in patients with no history of diabetes. In addition, many of these critically ill patients receive high-carbohydrate feedings in the form of total parenteral or enteral nutrition, which can contribute to increased BG levels.

The purpose of this project was to 1) continue the implementation of the IIP in the critical care units in a military inpatient setting and 2) evaluate the IIP in the critical care units.

This report includes data only for the insulin Infusion Protocol (IIP).

Methods

Members of the UPMC Diabetes Patient Safety Committee, in conjunction with the Medical Director and nursing staff of the UPMC Medical Intensive Care Unit, collaborated to develop the IIP. The IIP was evaluated at UPMC Hospitals. Findings from the evaluation suggested that the protocol was effective in achieving euglycemia while decreasing the number of adverse events [**14**]. Investigators from both UPMC and WHMC (UPMC and USAF staff) collaborated to modify the UPMC protocol for a military setting.

Inpatient Unit Training

The Glycemic Management Team trained the inpatient staff in three WHMC units: surgical intensive care unit (SICU); medical intensive care unit (MICU); and cardiac care unit (CCU). Training is made available at various times to accommodate staff rotation and deployment schedules.

Implementation

- In September 2007, the IIP was implemented in all critical care units at WHMC (CCU, SICU and MICU).
- Using previous and current BG levels, the insulin infusion is titrated according to protocol to obtain and maintain a target BG range of 80-130 mg/dL.
- In January 2009, the IIP BG target range was modified and implemented in all critical care units at WHMC (CCU, SICU and MICU). **The target BG range changed to 100-150mg/dL due to new published research** [**13**]**.**

Metrics

Metrics obtained for the IIP are as follows:

- The number of events due to hyperglycemia (BG >200 mg/dL; BG >180 mg/dL; BG >150 mg/dL) and hypoglycemia (BG < 40 mg/dL, BG < 60 mg/dl, BG < 70 mg/dL) were counted
- The time for BG levels to reach target BG ranges (80-130 mg/dL and 100-150 mg/dL) was calculated

- The percent of time BG levels within the target range was computed
- The frequency of IIP use was assessed
-

Analysis

Data was analyzed once the Glycemic Management Team was confident that the inpatient staff was able to appropriately use the IIP. Since there was a change in BG target range, the analysis was conducted separately for two cohorts:

- Data collected for patients admitted into the critical care units from May 2008 to December 2008 for a target BG range of 80-130 mg/dL
- Data collected for patients admitted into the critical care units from January 2009 to March 2009 for a target value of 100-150 mg/dL.

Measures of central tendency (percentages, means, or mediums) were used for descriptive analysis. Time to target BG range was calculated for those who were admitted with BG levels greater than the target range (i.e., > 130 or > 150 mg/dL). Time to target BG range was also calculated for those with a first event BG level greater than the target BG range. Hyperglycemic or hypoglycemic events are represented by the percent of patients who experienced at least one event. All analyses were conducted using SAS 9.2. (SAS Institute Inc., Cary, North Carolina)

Results

Because of the changes in target levels, results are presented for both glucose target ranges (80-130 mg/dL and 100-150 mg/dL).

Glucose Target (80-130 mg/dL) (Table 1)

As previously mentioned in this report, beginning in September 2007, the target BG range was changed to 80 - 130 mg/dL. Table 1 presents data for the IIP using this target BG range.

A total of 184 patients receiving inpatient treatment were placed on the IIP (131 SICU, 26 MICU, 27 CCU). The average age of those on the IIP was 58 years.

The majority of patients had type 2 diabetes (T2D). The average time to target BG range was 5.37 hours. The shortest average time to target BG range occurred in the CCU (4.78 hours).

Only twenty-eight percent (28%) of all patients across all three units experienced a hypoglycemic event (BG<60 mg/dL). The proportion was highest in the MICU (31%) and lowest in the CCU (26%). Patient BG levels were within target range 57% of the time across all units.

Length of stay (LOS) was stratified by vital status. Among survivors, the average LOS was four days with the longest LOS occurring in the SICU (4 days) and shortest in the CCU (3 days). LOS for those who died was 3 days.

Table 1: Results of WHMC IIP (May – December 2008)

Outcomes	CCU (n=27)	MICU (n=26)	SICU (n=131)	Total (n=184)
Age (years), mean±SD[a]	62.15±15.66	63.00±13.62	56.30±20.56	58.13±19.19
Gender, n (%)				
Male	16 (59.26)	9 (34.62)	91 (69.47)	116 (63.04)
Female	11 (40.74)	17 (65.38)	40 (30.53)	68 (36.96)
Type of diabetes, n (%)				
Type 1 diabetes	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Type 2 diabetes	16 (59.26)	11 (42.31)	47 (35.88)	74 (40.22)
Unknown	7 (25.93)	9 (34.62)	34 (25.95)	50 (27.17)
No diabetes	4 (14.81)	6 (23.08)	50 (38.17)	60 (32.61)
Time to goal BG at 80-130 mg/dL (hours), median (q1-q3)[b]	4.78 (3.92-9.91)	8.01 (3.95-11.99)	5.18 (2.81-8.11)	5.37 (3.02-8.60)
Hyperglycemia event, n (%)[c]				
BG>130 mg/dL	25 (92.59)	26 (100.00)	128 (97.71)	179 (97.28)
BG>180 mg/dL	21 (77.78)	21 (80.77)	89 (67.94)	131 (71.20)
BG>200 mg/dL	18 (66.67)	19 (73.08)	73 (55.73)	110 (59.78)
Hypoglycemia event, n (%)[d]				
BG<60 mg/dL	7 (25.93)	8 (30.77)	37 (28.24)	52 (28.26)
Percent of time goal BG at 80-130 mg/dL (%), mean±SD	54.04±27.68	52.27±23.82	58.78±20.74	57.16±22.33
Length of stay in ICU (days), median (q1-q3)[e]				
Overall	3 (2-4)	3.5 (2-8)	4 (2-8)	4 (2-7)
Live	3 (1.5-5.0)	4 (2-8)	4 (2-9)	4 (2-8)
Died	3 (2-4)	2 (2-3)	4 (2-7)	3 (2-6)

Values were reported as mean±SD, median (q1-q3), or number (%).
Abbreviations: BG, blood glucose; ICU, intensive care unit.
[a]There were two patients with unknown age in SICU.
[b]Time was calculated for the patients who were admitted into the ICU with the BG greater than 130 mg/dL and whose first event of the BG greater than 130 mg/dL. The number of such patients in CCU, MICU, and SICU were 23, 25, and 111, respectively.
[c]Hyperglycemia event was indicated by the percent of patients who developed at least one event.
[d]Hypoglycemia event was indicated by the percent of patients who developed at least one event.
[e]Among the total study patients in CCU, 20 patients were live, three died, and four were unknown regarding the vital status and the length of stay. Among the total study patients in MICU, 21 patients were live, three died, and two were unknown regarding the vital status and the length of stay. Among the total study patients in SICU, 108 patients were live and 23 died.

Glucose Target (100-150 mg/dL) (Table 2)

As previously mentioned in this report, beginning in January 2009 the target BG range was changed to 100 mg/dL-150 mg/dL.

A total of 46 patients receiving inpatient treatment (27 surgical, 9 medical, 10 cardiac) were placed on the IIP. The average age of those on the IIP was 58 years.

The majority of patients had T2D. The average time to target BG range (100-150 mg/dL) was 5.68 hours. The shortest average time to target BG range occurred in the CCU (3.89 hours).

Twenty-six percent (26%) of all patients across all three inpatient units experienced a hypoglycemic event (BG<60mg/dl). The proportion of patients experiencing a hypoglycemic event was highest in the MICU (44%) and lowest in the SICU (18.5%). Patient BG levels were within target range 52% of the time.

LOS was stratified by vital status. Among survivors the average LOS was five days. The longest LOS occurred in the CCU and MICU (6 days). The shortest LOS occurred in the SICU (3 days). LOS for those who died was 6.5 days. The largest difference between individual patients LOS, according to vital status, was observed in the SICU (3 days vs 7 days).

Table 2: Results of WHMC IIP (January – March 2009)

Outcomes	CCU (n=10)	MICU (n=9)	SICU (n=27)	Total (n=46)
Age (years), mean±SD[a]	67.00±17.36	59.33±11.31	55.77±18.89	58.80±17.52
Gender, n (%)				
Male	7 (70.00)	4 (44.44)	16 (59.26)	27 (58.70)
Female	3 (30.00)	5 (55.56)	11 (40.74)	19 (41.30)
Type of diabetes, n (%)				
Type 1 diabetes	0 (0.00)	0 (0.00)	1 (3.70)	1 (2.17)
Type 2 diabetes	6 (60.00)	5 (55.56)	12 (44.44)	23 (50.00)
Unknown	1 (10.00)	0 (0.00)	5 (18.52)	6 (13.04)
No diabetes	3 (30.00)	4 (44.44)	9 (33.33)	16 (34.78)
Time to goal BG at 100-150 mg/dL (hours), median (q1-q3)[b]	3.89 (2.19-12.18)	4.41 (1.03-10.60)	6.57 (1.80-9.99)	5.68 (2.00-10.30)
Hyperglycemia event, n (%)[c]				
BG>130 mg/dL	10 (100.00)	9 (100.00)	26 (96.30)	45 (97.83)
BG>180 mg/dL	9 (90.00)	9 (100.00)	18 (66.67)	36 (78.26)
BG>200 mg.dL	7 (70.00)	6 (66.67)	17 (62.96)	30 (65.22)
Hypoglycemia event, n (%)[d]				
BG<60 mg/dL	3 (30.00)	4 (44.44)	5 (18.52)	12 (26.09)
Percent of time goal BG at 100-150 mg/dL (%), mean±SD	52.46±16.93	57.88±12.89	50.30±24.55	52.25±21.06
Length of stay in ICU (days), median (q1-q3)[e]				
Overall	6 (4-9)	6 (1-10)	3 (2-9)	5 (2-9)
Live	6 (2-14)	6 (1-9)	3 (1-8)	5 (2-9)
Died	6.5 (4-9)	7 (4-10)	7 (2.5-14.0)	6.5 (3.5-10.5)

Values were reported as mean±SD, median (q1-q3), or number (%).
Abbreviations: BG, blood glucose; ICU, intensive care unit.
[a]There were two patients with unknown age: one was in CCU and the other was in SICU.
[b]Time was calculated for the patients who were admitted into the ICU with the BG greater than 150 mg/dL and whose first event of the BG greater than 150 mg/dL. The number of such patients in CCU, MICU, and SICU were 6, 7, and 19, respectively.
[c]Hyperglycemia event was indicated by the percent of patients who developed at least one event.
[d]Hypoglycemia event was indicated by the percent of patients who developed at least one event.
[e]Among the total study patients in CCU, seven patients were live, two died, and one were unknown regarding the vital status and the length of stay. Among the total study patients in MICU, five patients were live, two died, and two were unknown regarding the vital status and the length of stay. Among the total study patients in SICU, 23 patients were live and four died.

Insulin Infusion Protocol (IIP) Use

Table 3 represents the use of the IIP by inpatient staff in each unit. Percentages represent the total number of qualified patients placed on the IIP.

Patients must meet the following criteria to be placed on the IIP:

- BG level >200 mg/dL upon admission to inpatient units

or

- BG level > 130mg/dL (May-December 2008)/ >150 mg/dL (January-March 2009) upon admission to inpatient unit followed by additional BG levels > 130mg/dL (May-December 2008)/ >150 mg/dL (January-March 2009) measured every two hours

Table 3: Insulin Infusion Protocol (IIP) Use

Percent of Patients who Qualified & Placed on IIP			
	Percent of total qualified patients : CCU	Percent of total qualified patients : MICU	Percent of total qualified patients : SICU
May- Dec. 2008 (80-130 mg/dL)	35.6%	25.4%	22%
Jan-March 2009 (100-150 mg/dL)	23.3%	27.7%	27.3%

Summary

In summary, we were able to effectively use a Glycemic Management Team to train military staff at WHMC and implement the IIP. We will continue monitoring currently implemented protocols (IIP and Series 1) and continue to encourage protocol use in inpatient units.

KEY RESEARCH ACCOMPLISHMENTS

2. PEDIATRICS

Civilian Populations

- Refined and implemented HEROES, a peer intervention program, which resulted in improvement in patient compliance with lifestyle interventions and significant weight loss.
- Developed and implemented HB4Life, an integrated weight management Web portal, which serves as an educational resource to teach patients how to adopt lifelong healthy behaviors and as a site to track behaviors.
- Assessed clinical outcomes of the CHP diabetes prevention and weight management program. A significant percentage of patients successfully decreased their body weight, central adiposity, and blood pressure as a result of participating in program.
- Geographically expanded the Research Registry, successfully extending the reach of our CHP weight management program to communities throughout SWP.

Military Populations

- Translated and implemented CHP's weight management program for treatment of pediatric obesity in a military healthcare beneficiary population.
- Provided of obesity-related treatment to 207 military dependents.
- Integrated HB4Life into the weight management program at WHMC.
- Implemented the Research Registry to monitor WHMC clinical outcomes, learn about obesity phenotypes, conduct retrospective research studies, and recruit for prospective studies on obesity and related conditions.
- Recruited 87 participants into the Research Registry.

3. ADULT

PRIMARY PREVENTION

Civilian Populations

- Integrating LHW into a primary prevention team is feasible and valuable to participants.
- Participants in the GLB program reported satisfaction with the assistance of LHW and found them to play an important role in the GLB program.
- Measuring WC to determine T2D and CVD risk is a simple, non-invasive method that can be performed at the point of service in a community setting.
- WC is an effective method for identifying those at risk for T2D and CVD.
- Results suggest that GLB delivered via DVD was feasible to implement on a long-distance basis.
- Long-distance GLB-DVD was effective in reducing multiple risk factors for diabetes
- The GLB program was successfully implemented with long-distance support in the face to face delivery mode.

Military Populations

- Those participating in GLB programs at military facilities were satisfied with the GLB programs, lost weight and reduced metabolic syndrome risk factors
- Determined that the GLB delivered in the military-based setting appears to be considered a sound investment

- Determined that those who received GLB training were satisfied with the workshop trainings and are requesting additional trainings

CHRONIC CARE MODEL

Civilian Populations

- Determined through qualitative research with focus groups performed in rural underserved communities that:
  - Administrators want “low cost” interventions that can be sustained.
  - Patients life priorities as: jobs, insurance etc. Diabetes was considered hopeless and inevitable.

- PCPs perceived that their patients with diabetes have HbA1c, BP, and LDL at goal levels 25-50% of the time (data collected to date has not been concordant with this perception). This demonstrates the need for increased PCP practice support. Reaffirmed through focus groups that:
  - There is a shortage of endocrinologists, nurse educators and primary care physicians.
  - Concentration of health services available in urban area, but services sparse in the rural communities.

- Determined by using Geo-Information Systems analysis of 54,703 patients from nine PA counties that:
  - Many diabetes programs can be developed and implemented more efficiently at the local level.
  - While supermarkets and grocery stores were associated with a decrease in the likelihood of hypertension, hypercholesterolemia, being overweight and obese, the presence of convenience stores was associated with an increase in the likelihood of individuals having hypertension, hypercholesterolemia, being overweight, obese, and an HbA1c > 7.0%, after adjusting for individual and community level factors.
  - Full and limited-service restaurants presence was associated with a decrease in the likelihood of hypertension, being overweight and obese while the existence of fast food restaurants was associated with an increased prevalence.
  - Those who live more than 10 miles from their diabetes center are 88% more likely to have an HbA1c level > 7.0% as compared to those who live less than 10 miles from their center, adjusted covariates.
  - Residents of more rural counties are 11% more likely to be hospitalized for uncontrolled diabetes compared to those living in areas less rural.
  - Food and health care environment at the neighborhood level is a possible ecological determinant of health.

- Determined after audit and evaluation of clinical information systems (Delphi™ and AADE Outcomes System), that a:
  - Robust clinical information system that is accurate and user-friendly is required for PCPs and educators to be able to systematically collect and report diabetes data.
  - A system that helps educators to collect data and attain ADA education recognition, educators were able to demonstrate outcomes and reimbursement for services to sustain salaries support.
  - A system with a large data base to track and report diabetes behavioral and educational outcomes for advancing the practice of DSME is needed to demonstrate continued reimbursement.

- Patients who had access to team care and education services through a nurse-directed clinic and traveling educator teams had:
  - Significant reductions in HbA1c, LDL levels and weight.

- Through evaluation and cost-effectiveness analysis, we learned that:

- A multifaceted diabetes care intervention using the CCM (chronic care model) in the community PCP setting would be a sound, cost-saving investment as compared to the traditional provider continuing medical education processes.
- Compared to usual care, the CCM intervention was cost- effective.
- Implementation of the CCM intervention strategy in an underserved community was potentially cost-effective as compared to usual care.
- Compared to physician continuing education alone and usual care over a 3-year period, the CCM reduced the absolute incidence of micro-vascular or macro-vascular complications due to diabetes by 41.3% and 3.9% respectively.
- From a health care system perspective, the costs over 3 years for the CCM compared to usual care were $29,573 per diabetes complication averted.
- > 1/2 million health care dollars can potentially be saved while increasing the number of people who are at ADA target goals with access to team services in rural communities.
- Programs have great potential to continue to increase health savings over time.

- In working with stakeholders at the state level, we were able to:
  - Assist in the development of a state plan for diabetes in PA.
  - Work with the PA Commission on Chronic Care to deploy and evaluate the CCM in a statewide initiative.

- In our pilot study of telemedicine, we found that:
  - Patients, PCPs and the endocrinologist were highly satisfied and recommend further in-depth study.

- In testing and distributing the technology-based educational DVD, we:
  - Distributed 254 DVDs at the four PRIDE locations within a 3 month period.
  - Found that diabetes educators reported high satisfaction with the DVD tool.

Military Populations

WHMC DOC

- **9,318** physician visits were facilitated from January 2006 through December 2008.
- From our findings, mean patient HbA1c improved to 7.4%
- **1,143** patients have received DSME
- ADA DSME recognition was awarded May 2007
- Based on our findings in using the cost decision model, we have determined that the DOC operation would be considered a cost-saving endeavor.

WHMC DCOE

- Total number of patients seen, as of November 30, 2009: **1,031** (this number only represents visits for 2 UPMC NPs)
- Total referrals to DCOE as of November 30, 2009: **603**
- Diabetes Days ongoing at Goodfellow AFB; " Go Team" visits planned with:
  - Laughlin AFB
  - Kelly AFB
  - Randolph AFB
  - Naval Station Ingleside

- **135** patients at Goodfellow AFB receiving speacialty diabetes care services
- Goodfellow AFB patient baseline mean HbA1c 7.41%; **current follow-up mean HbA1c 6.88%**. 63% patient return for follow-up.
- 1,266 DVDs were distributed at WHMC within a three month period.
- Diabetes educators reported high satisfaction with DVD tool.

INPATIENT GLYCEMIC MANAGEMENT

Military Populations

- Established a Glycemic Management Team at WHMC
- Developed and provided training and education for inpatient staff at WHMC
- Implemented the IIP protocol in a military setting
- Began measurement of all implemented Series 1 protocols

REPORTABLE OUTCOMES

2. PEDIATRICS

Manuscripts (Publications)

Arslanian, S. Youth type 2 diabetes: Insulin resistance and insulin secretion. Commentary. International Diabetes Monitor. 2007;19(2):43-46.

Libman I, Arslanian S, Prevention and treatment of type 2 diabetes in youth. Hormone Res. 2007;67:22-24.

Rao G. Child obesity. Highlights of AMA expert committee recommendations. American Family Physician. 2009;78:56-66.

Rao G, Arslanian S. Office evaluation and management of the obese adolescent with metabolic syndrome. Obesity Management. 2009. (In Press).

Abstracts and Presentations

Rao G. Childhood obesity: Practical primary care approaches. AAFP Infant, Child, and Adolescent Medicine Conference. San Francisco CA. November 2007. Invited Lecture

Rao G. Childhood obesity: Practical primary care approaches. St. Vincent's Hospital Maternal-Child Health Seminar. Erie PA. May 2008. Invited Lecture

Rao G. Childhood obesity: Practical primary care approaches. Uniontown Hospital Grand Rounds. Uniontown PA. December 2008. Invited Lecture

Hannon T, Rofey D, Hull E, Vanderbilt-Adriance E, Arslanian S. Obstructive sleep apnea (OSA) and cognitive functioning in adolescents who are overweight. NAASO. 2008

Rofey D, Szigethy E, Noll R, Dahl R, Iobst E, Arslanian S. Reducing depression in adolescents with obesity: A cognitive behavioral approach. NAASO. 2008.

Kurland K, Hannon T, Rao G, Rofey D, Bacha F, Libman I, Arslanian S. Application of geographic information systems (GIS) mapping in a pediatric obesity center. The Pediatric Academic Societies Annual Meeting. Honolulu HA. 2008.

Lee S, Kuk J, Kim Y, Arslanian S. Measurement site of visceral adipose tissue and prediction of metabolic risk in black and white youth. American Diabetes Association 69th Scientific Sessions. New Orleans LA. 2009.

Drnach M, Krall J. Development and implementation of Web-based educational tools to address pediatric obesity. Accepted for presentation. NICHQ Annual Forum for Improving Children's Healthcare and Childhood Obesity Congress. Atlanta GA. 2010.

Arslanian S. Childhood and youth type 2 diabetes: The evolving picture. Global Diabetes Summit. Columbus OH. 2007. Invited speaker

Arslanian S. How the obesity epidemic is marring normal adolescent physiology. The Endocrine Society Hormones and Health Science Writers Conference. 2007. Washington DC. Invited speaker
Arslanian S. Obesity and comorbidities in youth. Pediatric Grand Rounds. Weill Cornell Medical College. New York NY. 2008. Invited speaker

Arslanian S. Type 2 diabetes in children. Endocrine Grand Rounds. Weill Cornell Medical College. New York NY. 2008. Invited speaker

Arslanian S. Treatment of type 2 diabetes in youth. Midwest Pediatric Youth Endocrine Society Meeting. Chicago IL. 2008. Invited speaker

Arslanian S. Do social/ethnic disparities influence the choice of treatment? ADA/SAH Consensus Conference on The Influence of Race, Ethnicity and Culture on Childhood Obesity: Implications for Prevention and Treatment. Los Angeles CA. 2008. Invited speaker

Arslanian S. Ethnic and pubertal differences in fat distribution and insulin resistance in children. Childhood Obesity: Genes, Brains and Behavior. USC Keck School of Medicine Symposium. Los Angeles CA. 2008. Invited speaker

Arslanian S. Type 2 diabetes in youth. Pediatric Grand Rounds. The University of Michigan Medical School. Ann Arbor MI. 2008. Invited speaker

Arslanian S. PCOS in adolescents. Pediatric Endocrinology Rounds. The University of Michigan Medical School, Ann Arbor MI. 2008. Invited speaker

Arslanian S. Obesity and the metabolic syndrome in children and adolescents: A tsunami in progress. The 111^{h} Annual Meeting of the Japan Pediatric Society. Tokyo Japan. 2008. Invited speaker

Arslanian S. Are obesity and metabolic syndrome stepping stones to the development of type 2 diabetes? CME Symposium. Pediatric Academic Societies and Asian Society for Pediatric Research Joint Mtg. Honolulu HA. 2008. Invited speaker

Arslanian S. The obese child with diabetes: What type is it and how to treat? 5th World Congress on Prevention of Diabetes and Its Complications. 2008. Helsinki Finland. Invited Speaker

Arslanian S. PCOS in adolescents. The Endocrine Society's 90th Annual Meeting. PCOS Across the Lifespan Symposium. San Francisco CA. 2008. Invited speaker

Arslanian S. Type 2 diabetes mellitus in children. The Endocrine Society's 90th Annual Meeting. Meet The Professor Session. San Francisco CA. 2008. Invited speaker

Arslanian S. Risk factors for cardiovascular disease in children with diabetes. ISPAD 34th Annual Meeting. Diabetes and Young Hearts: Perspectives on Glycemic Management and Cardiovascular Disease Risks. Durban South Africa. 2008. Invited speaker

Arslanian S. State of the Art Lecture: The metabolic syndrome in the pediatric age range. European Society for Pediatric Endocrinology (ESPE) Meeting, Obesity Club. Istanbul Turkey. 2008. Invited speaker

Arslanian S. Obesity & insulin resistance. American Academy of Pediatrics (AAP) National Conference & Exhibition (NCE). Boston MA. 2008. Invited speaker

Arslanian S. Glycemic control in children with type 2 diabetes. Cardiometabolic Health Congress. Boston MA. 2008. Invited speaker

Arslanian S. Type 2 diabetes in youth: The evolving picture. 13th International Congress of Endocrinology (ICE). Rio de Janeiro Brazil. 2008. Invited speaker

Arslanian S. Type 2 diabetes in youth: An evolving chameleon. Grand Rounds. Baylor College of Medicine. Houston TX. 2008. Invited speaker

Arslanian S. 1. Modern management of type 2 diabetes in youth; 2. Pathogenesis & pathophysiology of Type 1 diabetes mellitus; 3. Screening/prevention of T2DM in youth: The American Experience. European Association for the Study of Diabetes (EASD)/Chinese Diabetes Society (CDS)/Lilly Postgraduate Course. Beijing China. 2008. Invited speaker

Arslanian S. Type 2 diabetes in youth: A pediatrician's nightmare. Endocrine Grand Rounds. University of Kentucky. Louisville KY. 2009. Invited speaker

Arslanian S. The metabolic syndrome in pediatrics. Endocrine Conference. Children's Hospital of Los Angeles, Keck School of Medicine. Los Angeles CA. 2009. Invited speaker

Arslanian S. Role de la puberte' dans le development de l'insulinresistance. Diabetologic Congres Francophone Annual. ALFEDIAM. Strausbourg France. 2009. Invited speaker

Arslanian S. Insulin resistance, components of the metabolic syndrome & biomarkers of endothelial dysfunction in youth. 3rd International Congress on Pediatrics & the Metabolic Syndrome. 2009. Nice France. Invited speaker

Arslanian S. Obesity and insulin resistance in youth. CME –The University of Chicago Biological Sciences. New Approaches in Endocrinology: Transition From Pediatric to Adult Care. 2009. Chicago IL. Invited speaker

Arslanian S. Pediatric diabetes: What type of diabetes is it: Type 1, type 2 or another type? 7th Annual EFF/ADA Endocrine Fellows Forum. 2009. New Orleans LA. Invited speaker

Arslanian S. Type 2 diabetes mellitus in children. The Endocrine Society's 91st Annual Meeting. Meet the Professor Session. 2009. Washington DC. Invited speaker

Arslanian S. Type 2 diabetes in youth: The pediatrician's nightmare. 10th Armenian Medical World Congress. 2009. New York NY. Invited speaker

Funding

01/08-12/10
Are overweight children with T1DM at increased risk of cardiovascular disease?
Source: ADA Junior Faculty Award
Principal Investigator: Ingrid Libman M.D. PhD.
Mentor for Ingrid Libman, M.D. PhD.

07/08-06/11
Are overweight children with T1DM at increased risk of cardiovascular disease?
Source: NIH-1K23HL085287-01A2
Principle Investigator: Ingrid Libman M.D. PhD.
Mentor for Ingrid Libman, M.D. PhD.

07/08-06/11
Physical activity in youth: Implications for reversing risk factors for type 2 diabetes
Source: ADA Junior Faculty Award
Principle Investigator: SoJung Lee, PhD.
Mentor for SoJung Lee, PhD.

07/07-06/09
Impaired sleep, Insulin action and overweight in youth
Source: The Pittsburgh Foundation
Principle Investigator: Tamara Hannon, M.D.
Mentor for Tamara Hannon, M.D.

01/08-present
Healthy bodies, healthy minds: Helping adolescents with polycystic ovary syndrome
Source: BIRCWH, K12
Principle Investigator: Dana Rofey, PhD.
Mentor for Dana Rofey, Ph.D.

07/09-present
Healthy bodies, healthy minds: Helping adolescents with polycystic ovary syndrome
Source: K23
Principle Investigator: Dana Rofey, PhD.
Mentor for Dana Rofey, PhD.

3. ADULT

PRIMARY PREVENTION

Civilian Populations

Manuscripts (Publications)

Kramer M, Kriska A, Venditti E, Miller R, Brooks M, Burke L, et al. Translating the diabetes prevention program: A comprehensive model for preventionist training and program delivery. Am J Prev Med. 2009;37(6)

Abstracts and Presentations

Piatt G, Sesay M, Powell R. Participant satisfaction with the use of lay health coaches in a modified diabetes prevention program. Submitted. CDC Division of Diabetes Translation Annual Meeting. Kansas City MO, April 2010.

Kramer M, Miller R, Orchard T. Relationship of health-related quality-of-life to participation in a modified diabetes prevention program intervention. American Diabetes Association 69th Scientific Sessions. New Orleans LA, June 2009. Accepted for publication June, 2009.

Kramer M, McWilliams J, Siminerio L. Diabetes educators implementing primary prevention: The group lifestyle balance program. Submitted. CDC Division of Diabetes Translation Annual Meeting. Kansas City MO, April 2010.

Kramer M, Venditti E, Kriska A, Orchard T. Group lifestyle balance DVD: A novel media approach to implementing primary prevention. Submitted. CDC Division of Diabetes Translation Annual Meeting. Kansas City MO, April 2010.

Kramer M, Kriska A, Venditti E, Siminerio L, Orchard T. Translation of a modified diabetes prevention program lifestyle intervention: The group lifestyle balance program. Submitted. 6th World Congress on Prevention of Diabetes and its Complications. Dresden Germany, April 2010.

Piatt G, Seidel M, Zgibor J. Using waist circumference as a valid screening method to identify diabetes and/or cardiovascular disease risk in an urban, underserved community. American Diabetes Association 69th Scientific Sessions. New Orleans LA, June 2009.

Seidel M, Piatt G. Translational research in diabetes prevention: Opportunities for dietitians. Food and Nutrition Conference and Exhibition Annual Meeting. Denver CO, October 2009.

Kramer M, et al. Translating the diabetes prevention program lifestyle intervention to a real world health care setting. American Heart Association 49th CVD Epidemiology and Prevention/Nutrition, Physical Activity and Metabolism Joint Conference. March 2009. Oral Presentation.

Kramer M, et al. Translation of the diabetes prevention program (DPP) lifestyle intervention to the real world. Pennsylvania State University Diabetes and Obesity Research Retreat. State College PA, March 2009. Oral Presentation

Kramer M, et al. Translation of the diabetes prevention program (DPP) lifestyle intervention to the real world. Pennsylvania State University Diabetes and Obesity Research Retreat. State College PA, March 2009. Poster Presentation

Kramer M, et al. Translating an evidence-based strategy for diabetes prevention: Research to real world invited lecture. Montana Cardiovascular Health Summit. Missoula MT, April 2009. Invited Lecture

Kramer M, Kriska A, Venditti E, Orchard T. Development of training and support for translation of a modified DPP lifestyle intervention. CDC Division of Diabetes Translation Conference. Los Angeles CA. April 2009. Oral Presentation

Kramer M, Miller R, Kriska A, Venditti E, Orchard T. Self-monitoring of food intake, physical activity levels and weight in a modified DPP lifestyle intervention. CDC Division of Diabetes Translation Conference. Los Angeles CA. April 2009. Poster Presentation

Kramer M, Miller R, Orchard T. Relationship of health-related quality-of-life to participation in a modified diabetes prevention program intervention. American Diabetes Association 69th Scientific Sessions. New Orleans LA. June 2009. Poster Presentation

Patents

- Establishment of licensing to protect the integrity of the Group Lifestyle Balance Program.

Degrees

- Robert Powell, Program Manager, while on 06 funding to work as the associate Program Manager and then Program Manager of the Braddock UPDI Community Team received an MS degree in Exercise Physiology from the University of Pittsburgh.

Funding

Kriska A (PI). Translational research for the prevention and control of diabetes and obesity (R18). National Institutes of Health. Healthy LIFESTYLE Project. (Submitted but not yet funded - Received good score)

Siminerio L (PI). Diabetes educators as preventionists: Translating a modified diabetes prevention program (DPP). Sanofi-Aventis. Funded and ongoing.

Orchard T (PI). Evaluation of group lifestyle balance maintenance strategies. Atkins Foundation. Funded and ongoing.

Employment or research opportunities

- DPSC and UPDI-faculty working with CDC toward development of national diabetes prevention model for training and recognition.
- Hospital and health plan cooperative implementation: Beaver County, PA
- Employee program: UPMC North West
- Out-patient community funded: Armstrong County Memorial Hospital
- African American Churches: Augusta, GA
- Network of Rural Senior Centers: Little Rock, AR
- Health Care Organization Evaluation of Online GLB: Palo Alto, CA
- Large health care organization: Sacramento, CA
- Boston, MA: Genetics Project

University of Pittsburgh investigators, Drs. Kaye Kramer, Elizabeth Venditti and Linda Siminerio are participating with an invited team organized by the CDC to determine strategies for primary prevention and recognition programs for training.

Military Populations

- Training on the GLB program was provided to those providing services to the military
- The Virtual Lifestyle Manager and GLB CD-ROM were tested in feasibility studies with the USAF and are available

Manuscripts (Publications)

McTigue K, Bhargava T, Bryce C, Conroy M, Fischer G, Hess R, et al. "She actually hugged me" – Patient perspectives on the integration of an intensive online behavioral weight loss intervention into primary care. Patient Education and Counseling. (Submitted)

McTigue K, Conroy M, Simkin-Silverman L, Bryce C. Fiorillo A, Fischer G, et al. Virtual Lifestyle Management: Translation of an intensive lifestyle intervention to an online setting. Ann Beh Med. 2008;35:S167.

Abstracts and Presentations

Bhargava T, McTigue K, Bryce C, Conroy M, Fiorillo A, Fischer G, et al. Patient satisfaction with an Internet-based approach to translating a proven lifestyle intervention into clinical practice. CDC Diabetes Translation Conference 2009. Los Angeles CA. April 2009. Oral presentation.

Bhargava T, McTigue K, Bryce C, Conroy M, Fiorillo A. Fischer G, et al. Patient satisfaction with an Internet-based approach to translating a proven lifestyle intervention into clinical practice. University of Pittsburgh Graduate School of Public Health, Dean's Day. Pittsburgh PA. March 2009. Oral presentation.

McTigue K, Conroy M, Simkin-Silverman L, Bhargava T, Bryce C, Fiorillo A, et al. Too busy for a health lifestyle? An online program can promote weight loss. CDC Diabetes Translation Conference 2008. Orlando FL. May 2008. Oral presentation.

Awards

Drs. McTigue, Conroy and Simkin-Silverman were recognized by the University of Pittsburgh for their work in developing and licensing the online adaptation of the VLM curriculum. They each received a "Pitt Innovator Award" in 2008.

Funding

McTigue K (PI). Online counseling to enable lifestyle-focused obesity treatment in primary care. AHRQ 1R18HS018155-01. 9/30/2009-7/31/2012. This study will examine the effectiveness and cost-effectiveness of using two different online coaching strategies with an online lifestyle intervention in primary care patients. It uses technology to enable the translation of a validated intervention into a clinical setting.

CHRONIC CARE MODEL

Civilian Populations

- Established four diabetes clinics in PRIDE communities
- Developed the Chronicle data management system
- Participated in the PA Diabetes Action Plan and PA Governor's Chronic Care Model Commission
- Established Telemedicine Program
- Created educational DVDs

Manuscripts (Publications)

Trauth J, Terry M, Keane C, Jaros K, Piatt G, Siminerio L. Exploring the meaning of the chronic care model's community construct: A study of diabetes self-management support. Am J. of Public Health. Under Review.

Siminerio L, Wagner E, Gabbay R, Zgibor J. Implementing the chronic care model: A statewide focus on improving diabetes care in Pennsylvania. Clinical Diabetes. 2009:27;153-59.

Peyrot M, Rubin R, Funnell M, Siminerio L. Access to diabetes self management education: Results of national surveys of patients, educators and physicians. The Diabetes Educator. 2009;35(2):246-63.

Smith K, Hsu H, Roberts M, Kramer M, Orchard T, Piatt G, et al. Cost-effectiveness analysis of efforts to reduce risk of type 2 diabetes and cardiovascular disease in the community. Preventing Chronic Disease. (Under Review).

Abstracts and Presentations

Bettencourt L, Uhler A, Ruppert K, Zgibor J, Siminerio L, Piatt G. Implementing the chronic care model in a rural healthcare setting to improve the ABCs of diabetes author block. American Diabetes Association 68th Scientific Sessions. San Francisco CA, June 2008.Poster Presentation

Siminerio L. Pennsylvania diabetes prevention and control program; Pennsylvania diabetes action partnership members. Building the Pennsylvania diabetes action plan. CDC Division of Diabetes Translation Conference. Orlando FL, May 2008. Oral Presentation

Piatt G, Harding C, Noullet W, Siminerio L. Enhancing diabetes self-management education through the use of a clinical information system in an underserved, rural community. American Diabetes Association 69th Scientific Sessions. New Orleans LA. June 2009. Poster Presentation

Ruppert K, Siminerio L, Stewart A, Sebesta B, Trott V, Songer T. Diabetes education services and health care charges in a large health system database. American Diabetes Association 69th Scientific Sessions. New Orleans LA. June 2009. Oral Presentation

Siminerio L, Gabbay R. Implementing the chronic care model for improvements in diabetes care:
A prescription for Pennsylvania. International Diabetes Foundation. International Diabetes Foundation 20th World Diabetes Congress. Montreal Canada. October 2009. Oral Presentation

Hsu H, Smith K, Roberts M, Kramer M, Orchard T, Piatt G, et al. Cost-effectiveness analysis of community-based efforts to prevent diabetes. Society for Medical Decision Making 29th Annual Meeting. Pittsburgh PA. October 2007. Poster Presentation

Kuo S, Smith K, Zgibor J, Piatt G, Roberts M, Bryce C. Cost-effectiveness of implementing the chronic care model for diabetes care in the community. Society for Medical Decision Making 31st Annual Meeting. Hollywood CA. October 2009. Poster Presentation

Awards

Siminerio, Linda. Distinguished Service Award presented by the AADE. August, 2008.

Funding

Piatt G. et al. International Diabetes Federation (IDF) BRIDGES (Bringing Research in Diabetes to Global Environments and Systems) Grant. Integrating and evaluating peer education in a diabetes care delivery system. (Approved 2009)

Siminerio L, et al. NIH Challenge Grant. Web-based diabetes patient support for sustained self-management and education. (Submitted)

Highmark Foundation Grant. Improve access to diabetes care and services. Awarded to: Meyersdale Medical Center for the development of the health education for life pre-diabetes program; Miners Medical Center for the development of the plan for improving health status of diabetic populations.

Military Populations

- Established diabetes clinic at WHMC
- 30 employees currently staff the DCOE

Abstracts and Presentations

Kuo S, Zgibor J, Wolf D, Roberts M, Bryce C, True M, et al.. Benefits of implementing the diabetes outreach clinic for diabetes care. American Diabetes Association 69th Scientific Sessions. New Orleans LA. June 2009. Poster presentation.

Degrees

Total number of fellows during DOC years: 8
Currently 4 fellows rotating in DCOE (2 are 2nd year, so were here in 2008 too)

Informatics

Educational DVD has been submitted to the National Diabetes Education Program for review and potential inclusion in their program.

INPATIENT GLYCEMIC MANAGEMENT

Military Populations

- Developed glycemic management protocols
- Established a Glycemic Management Team
- Employed 2.5 staff for Glycemic Management Team

CONCLUSIONS

We implemented our prevention and treatment strategies based on the Strategic Plan and continued to reexamine our processes and progress throughout the term of this project. In keeping with strategies in the development of a national model, we organized a diabetes planning meeting with diabetes experts representing institutions and organizations, regionally and nationally. At the meeting we reviewed progress to date on our pediatric and adult projects. We organized an Advisory Group to continue to provide advice for project development that meets the needs of the nation. A summary of the meeting is presented in *Appendix C*.

Pediatric

Since the inception of the CHP pediatric diabetes prevention and weight management program, our mission has been the advancement of the clinical care of children with obesity and research into the causes, complications and prevention of childhood obesity. Support from this award enabled us to develop and expand our program's scope and reach. Specifically, we refined and tested HEROES, a peer group intervention; assessed clinical outcomes; developed and implemented the HB4Life program, an integrated weight management Web portal; and geographically expanded the Research Registry.

Our research demonstrated that refinement of the HEROES program appeared to positively influence program effectiveness. Participant and parental compliance improved and a significant proportion of participants decreased their weight while participating in HEROES. As a result of participating in the CHP diabetes prevention and weight management program, a significant percentage of patients successfully decreased their body weight, central adiposity, and blood pressure. These findings emphasize the benefit of early detection followed by family-based lifestyle intervention as an effective method of pediatric obesity treatment and chronic disease prevention. In addition, the HB4Life program provided as an educational resource to teach patients how to adopt lifelong healthy behaviors and as a site to track behaviors (via Healthy Plate and Big 5 Tracker) across time. Provision of data on the web-based educational tools facilitated and guided wellness advice in follow-up clinic visits. Finally, through our Research Registry and close follow-up and tracking of participants in this Registry, we continuously modify and individualize intervention strategies to optimize delivery of care, with an ultimate goal of creating a national model for diabetes prevention in children.

We also successfully translated and implemented the CHP diabetes prevention and weight management program into a military setting. HLP clinic-based intervention strategies and the HB4Life program were adopted for use at the SAMPC Pediatric Wellness Center at WHMC, allowing us to address pediatric obesity in a military healthcare beneficiary population. In addition, we implemented the Research Registry at WHMC and recruited a representative sample of the patient population into the Registry, which will continue to grow. The Registry will be utilized to provide meaningful data regarding the causes and treatment of childhood obesity of military dependents.

Adult

During this cycle of funding, in the adult and military populations we have demonstrated positive findings in several areas. In testing primary prevention strategies based on the DPP, we were able to successfully train interested parties in both civilian and military sites on the DPP GLB program. We also identified new approaches that facilitate screening opportunities and support mechanisms. We showed that waist circumference could be used as a proxy for identification of those at risk and lay health coaches can assist at risk individuals with lifestyle changes.

Through the evolution of this program, we have tested strategies in civilian populations to later implement them in a military community. We were able to demonstrate the effectiveness of implementing the GLB through several

technological methodologies in civilians. Although our recruitment numbers were lower in the military sites because of some logistical barriers, we were able to demonstrate effectiveness, satisfaction and interest.

The Chronic Care Model provided an effective model for treatment strategies in underserved rural populations in PA. We were able to report improved clinical outcomes and potential cost savings. We communicated our success to leadership organizing state efforts that are subsequently deployed and evaluated statewide. We addressed the national crisis with shortages of diabetes specialists, like diabetes educators and endocrinologists. We delivered a self-management education system to the American Diabetes Association that is expected to be deployed nationwide to diabetes educators and a telemedicine program that was well-received by an endocrinologist, primary care providers and patients in an underserved community.

We translated our success with the Chronic Care Model into a military clinic at Wilford Hall Medical Center (WHMC). We organized a Diabetes Outreach Clinic, established recognition for a diabetes self-management education program, and disseminated educational self-management tools to units and clinics. We were able to effectively use a Glycemic Management Team to train military staff, evaluate an insulin infusion protocol and continue to monitor a series of glycemic protocols in military inpatient units.

Given the described limitations, it appears that implementing our evidence-based programs can be considered a sound investment from a cost perspective. We maintain our national presence in working with the ADA, CDC, other academic institutions and military branches. We continue to determine strategies for effective primary prevention and treatment for children and adults for civilians and military beneficiaries as our nation addresses the ever-growing epidemic of obesity and diabetes.

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ADULT

Chronic Care Model

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Appendices

Appendix A. Strategic Plan

UPMC Strategic Plan for a National Model for Diabetes Prevention and Treatment in Civilian and Military Healthcare Beneficiary Populations

UPMC

UPMC

University of Pittsburgh Diabetes Institute

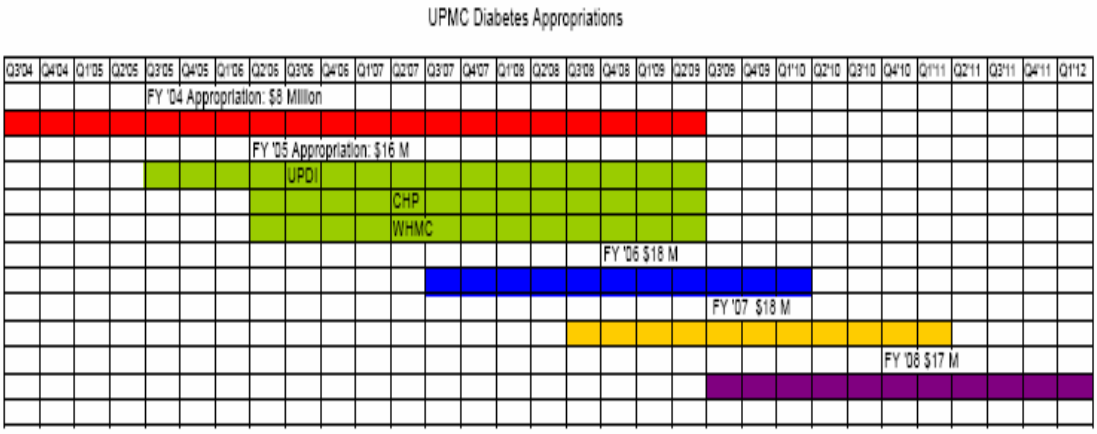
I. Executive Summary:

Diabetes is a major public health problem throughout diverse population groups and geographic areas. Unfortunately, traditional models of medical care are ineffective to address the clinical and behavioral antecedents of this, as well as many other chronic diseases. The purpose of this project is to evaluate the applicability and effectiveness of specific interventions as well as models for treatment and prevention in various settings within the civilian and military populations. Leadership and resources provided by centers of excellence in the civilian and military sectors will continuously advance evidence-based care and promote efficiencies and sustainability.

The strategic plan has been developed by UPMC in collaboration with its civilian and military partners as a mechanism for summarizing the work to date on the project, communicating project initiatives to key stakeholders, and forming a dynamic management tool to provide general direction as the project moves ahead. It is anticipated that this document will be continuously revised and expanded as work evolves and research results become available.

Overview of the Project:

The chart immediately below illustrates the timeline of current and potential project funding.



Key initiatives of the appropriation funding cycles include:

FY '04 Appropriation

Establish the project infrastructure. Develop prevention and treatment tools and mechanisms for deploying them to project participants. Establish relationships with communities in western Pennsylvania and initiate programming for prevention and treatment. Establish the Diabetes Outreach Clinic at Wilford Hall Medical Center (WHMC).

FY '05 Appropriation

Implement the weight management center at Children's Hospital of Pittsburgh. Implement programming and obtain certification for sites in Western Pennsylvania. Evaluate and refine prevention and treatment tools and implement dissemination mechanisms. Implement tools to support assessment of outcomes in civilian sites. Develop and implement tools for retinal screening in primary care and community settings. Implement the DOC and determine needs for a weight management center and other pediatric services at WHMC.

FY '06 Appropriation

Expand the scope of services associated with pediatric weight management, including development of a weight management center at WHMC. Determine outcomes of prevention and treatment initiatives in western PA and align initiatives with the PA Diabetes Plan. Develop a Center of Excellence at WHMC and evaluate the needs at other selected military bases.

FY '07 Appropriation

Assess the outcomes of pediatric weight management initiatives. Establish a pediatric center of excellence at WHMC. Using evaluation data from prior project years, continue to refine programming. Expand prevention and treatment initiatives to other geographic areas in the military and civilian populations, through on-site programming, remote consultation, and web-based tools.

FY '08 Appropriation

Develop and begin to implement plans for project sustainability. Expand the multi-disciplinary nature of care delivery. Evaluate the impact of the PA Diabetes Plan on sites within the state. Expand programming to special populations within the civilian sector and other branches of the military.

FY '09 Appropriation

Define strategies for third party reimbursement of prevention and treatment services. Achieve national dissemination of prevention and treatment models in civilian and military populations, in a manner that allows adaptation to the needs of specific sites and population groups.

FY '10 Appropriation

Perform a comprehensive summary of project outcomes. Implement a sustainability plan in military and civilian sites.

II. Introduction

Diabetes and its antecedents (such as obesity) lead to serious complications and are pressing public health agendas in the United States and across the globe, becoming the chronic disease endemic and has consequences for the civilian and military populations. No longer limited to the adult populations,

obesity and diabetes are becoming increasingly prevalent in children and adolescents. The economic and societal burden created by this public health problem cannot be under-estimated, affecting not only quality of life and morbidity and mortality but also straining the country's healthcare resources and the productivity of our private and public sectors. This problem is particularly acute for the military, with the potential to impair the physical capabilities of the recruiting pool, limit the battle-readiness of its fighting forces, and create significant disease burden and healthcare costs for dependents, retirees, and veterans.

Current medical models of care are inadequate to address this chronic disease epidemic. Although modern advances in therapy can improve glycemic control and palliate complications, definitive strategies for prevention and treatment must address lifestyle and behavioral issues and offer comprehensive, multi-disciplinary clinical services. Unfortunately, the development of such initiatives has been hindered by barriers such as lack of reimbursement for preventive and primary care services, insufficient critical evaluation of innovative practices, and shortages and mal-distribution of specialty and other expert resources.

The University of Pittsburgh Medical Center (UPMC) and its affiliate, the University of Pittsburgh, have gained international recognition for investigation of the pathophysiology of diabetes, development and dissemination of tools for prevention, use of information technology and telecommunications to advance clinical care and distribute specialty resources, deployment of new models of care in diverse settings. Beginning in 2004, funding from the Department of Defense to the UPMC, University of Pittsburgh, and Children's Hospital of Pittsburgh has supported the synthesis and integration of this expertise and experience into prototype care models in underserved communities and the military that offer great promise for preventing and treating diabetes. As the project commences its third funding cycle (the FY '06 appropriation) it is appropriate to further refine the anticipated short- and long-term goals, in order to assure a coherent and shared vision among UPMC, its military partners, and key stakeholders.

The vision for the project is to establish comprehensive, effective, sustainable models for prevention and treatment of diabetes that can be deployed in diverse settings among disparate civilian and military populations. This will be accomplished through use of evidence-based, multi-disciplinary health care services that are supported by electronically-based tools and specialty expertise in national centers of excellence.

During the first two funding cycles, the following projects were implemented, evaluated and served as the foundation for expanded programs:

- The Chronic Care Model (CCM), a comprehensive health care delivery model, was implemented and evaluated in rural sites in western Pennsylvania and in a diabetes clinic based at the AF Wilford Hall Medical Center.
- Within the structure of the CCM, a number of diabetes clinics and programs were established and evaluated, that include but are not limited to nurse-directed clinics, group medical visits for chronic disease management, and traveling educators to primary care
- A weight management center was instituted at the Children's Hospital of Pittsburgh.
- A web-based weight management tool to address the needs of children and parents regarding obesity was created.
- A tele-monitoring system was developed and evaluated at the Pittsburgh VA Health System to support outreach services for home bound veterans with diabetes.
- A diabetes self-management web-based tool was designed and evaluated for national implementation through the American Association of Diabetes Educators (AADE).

- A patient portal (Health Trak) linked to an electronic medical record was designed and evaluated to promote increased opportunities for patient diabetes self-care.
- A comprehensive retinal imaging program was developed to support eye exams through mobile units in underserved communities.
- A diabetes prevention curriculum was developed, implemented, and evaluated based on the National Diabetes Prevention Program.
- An online prevention program, the Virtual Lifestyle Manager, was created.
- A screening tool was developed to identify people at risk in primary care practices.
- A Physical Activity Resource Center (PARC) was established to support the deployment of evidence-based diabetes prevention tools and programs.
- Community Outreach and education were implemented through public awareness and educational events throughout western PA.
- A diabetes prevention program was implemented and evaluated in an underserved, high risk, urban community.

All of these programs and tools to support prevention and treatment have been developed, refined, and deployed with the intent to have applicability at the local, project, and national levels. Over the ensuing funding years, prevention and treatment initiatives will be extended to other civilian and military populations, with guidance and support provided by centers of excellence in Pittsburgh and San Antonio. By the completion of the seventh funding cycle (potential FY 2010 appropriation), it is anticipated that effective, sustainable models for prevention and treatment will be implemented in both the civilian and military sectors.

III. Vision Statement:

To implement a national model in which efforts are directed toward the prevention and treatment of diabetes in civilian and military populations. This model will employ enabling tools and strategies that modify behavior and promote healthy lifestyles in both children and adults as well as comprehensive, multi-disciplinary systems of care that can be deployed in various geographic and demographic settings. This model will provide people at risk or with Diabetes with the best available expertise, regardless of where or when they enter the system, and will demonstrate sufficient impact on the cost, quality, and accessibility of care to justify sustainable financing from both the governmental and private sectors.

IV. Mission Statement:

Through support from the Department of Defense and collaboration with its military partners, UPMC will develop comprehensive systems for the prevention and treatment of diabetes that are based on the best available evidence, draw on the expertise of multiple professional disciplines, support statewide and national policy priorities, and translate to all segments of the civilian and military populations. National centers of excellence within the military and civilian sectors will provide support and expertise to identified outreach sites, evaluate clinical and fiscal outcomes, and advance the national diabetes community agenda.

V. Values:

In order to carry out its mission and achieve its vision, the project is committed to the following values:

- Provision of the best quality care to all segments of the civilian and military populations through the implementation of translatable models and innovative approaches.
- Application of the best available literature and evidence.
- Conduct of rigorous evaluation and outcomes measurement.
- Transparent and open collaboration with military and other partners that include diabetes representative organization, like the American Diabetes Association (ADA), the Center for Disease Control (CDC), and the AADE.
- Adaptation of programmatic goals based on outcomes evaluation, needs of partnering organizations and other stakeholders, statewide and national policy priorities, and shifting population demographics.
- Open sharing of outcomes and widespread dissemination of results through presentations and publications.
- Responsible stewardship of federal funding and full compliance with all regulatory requirements.

VI. Process for Strategic Planning:

As the FY '05 projects rolled out, UPMC worked closely with its military partners to create a vision and strategy for deployment of the prevention and treatment models. A series of strategic planning meetings have been conducted to develop the concepts and action steps defined in this plan:

- February 27-28, 2007: Wilford Hall Medical Center, San Antonio, TX
- August 21, 2007: Skyline Office, Falls Church, VA
- September 10, 2007: UPMC, Pittsburgh, PA
- November 14, 2007: Wilford Hall Medical Center, San Antonio, TX

Additional meetings were conducted at Fort Detrick, MD on November 26, 2007 to discuss inter-service participation in the project and on December 18, 2007 at Brooks City Base in San Antonio to better understand Col. Masterson's vision for the project.

Membership of the strategic planning team has been as follows:

- UPMC: Dr. Barbara Barnes, MD (chair); Dr. Linda Siminerio, PhD (University of Pittsburgh PI), Loren Roth, MD (executive project director, emeritus), Trevor Orchard, MD (PI, primary prevention), Mary Korytkowski, MD (PI, inpatient initiatives), Mark Roberts, MD (representing the evaluation team), Mr. Michael Drnach (representing the pediatric obesity and diabetes management initiative), Janice Zgibor, PhD (UPDI Evaluation Core), Ms. Suzanne Sakson (UPDI Project Director), Mr. Ronald Dornin (executive project director), Jonathan Stapley, PhD (UPMC executive administrator at WHMC), and Ms. Tanya Crail (WHMC clinical operations).
- US Air Force: Major Mark True (WHMC adult diabetes services), Col. Mary Pelszynski (WHMC pediatric services), Lt. Col. Deborah Malone (prior subject matter expert, SGR-M), Lt. Col. Gregory Dye (prior subject matter expert, SGR-M), Ms. Tess Ellis (SGR-M), Ms. Deanie Hurst (SGR-M), Ms. Geri Wilbur (SGR-M), and Mr. James Mason (SGR-M)

VII. Strategies:

A number of core strategies and guiding principles are being used in this project, including:

- *Implementation of Centers of Excellence*: Due to the short supply and mal-distribution of specialty resources in both military and private settings, the project will establish centers of excellence (COE's) in Pittsburgh and San Antonio that will provide human, information, and programmatic resources to sites throughout the country. Multi-professional assessment teams will offer site assessments and assist local providers in developing the scope of services required by their individual patient populations. The COE's will also be responsible for advancing the strategic interests of the project, advocacy with regulators and payers, and dissemination of project outcomes.

- *Development of web-based tools to support primary care practice and advance patient empowerment*: Tools to support prevention (e.g., PARC, those associated with the modified Diabetes Prevention Program (mDDD), and the Healthy Lifestyle Program (HLP) pediatric program) and treatment will be presented to sites across the country.

- *Design and implementation of multi-disciplinary models of prevention and treatment*: To support prevention initiatives and the CCM, critical evaluation (in terms of clinical outcomes, patient satisfaction and cost-effectiveness) will be performed to determine ideal staffing complements in various settings. Innovative models, such as use of diabetes educators to perform retinal screenings, will also be assessed. The results of these studies will be used to advocate for reimbursement of effective services and regulatory support of appropriate scopes of practice.

- *Deployment of IT infrastructure to support analysis of outcomes at the practice, institutional, regional and national levels:* The capabilities of electronic medical records (EMRs) and data management systems used in the private and military sectors will be evaluated to determine capacity to produce data and reports related to the quality and cost of diabetes prevention and treatment services. Collaboration will be forged with national organizations to explore opportunities for national data repositories to track and assure local and national data quality of care.

- *Development and implementation of evidence-based protocols and guidelines:* In order to promote high quality and cost-effective care, protocols and guidelines will be tested by the COE's and distributed to sites, as appropriate to their specific patient population.

- *Customization of care to meet the needs of special populations and accommodate local resource constraints:* The project will be deployed in a variety of geographic areas to diverse demographic groups in order to determine specific requirements and necessary adaptations to assure culturally appropriate care and optimal use of resources.

- *Procurement of certifications and recognitions:* The project will assist civilian and military healthcare providers in meeting requirements for national professional organizations (e.g., ADA and AADE) in order to promote high quality care and adequate reimbursement.

- *Rigorous, multi-faceted evaluation and dissemination of results:* Assisted by expertise from the University of Pittsburgh, the project will employ appropriately robust measures to assess clinical and fiscal outcomes. These results will be shared with partners and disseminated through presentations at national and international professional meetings and published in peer-reviewed journals.

- *Collaboration with other national stakeholders*: Project leadership will work closely with other experts in the field to identify best practices and avoid duplication of effort.

- *Commitment to sustainability:* The models of prevention and treatment developed in this project are developed to have the capability of being feasibly deployed in diverse settings and considered for financial and programmatic support once DoD funding has been completed.

VIII. Action Steps:

Through the processes described above and based on the strategic principles of the project, Appendices 1 through 4 present strategic schema and Appendices 5 and 6 present respective budgetary Rough Order of Magnitudes (ROM) for prevention and treatment of obesity in children, primary prevention of diabetes, treatment of diabetes through use of the chronic care model, and inpatient treatment of diabetes in the civilian and military populations.

IX. Strengths, Weaknesses, Opportunities and Threat (SWOT) Analysis:

Given the public health impact of diabetes, the changing healthcare environment in the United States, and the size and complexity of this project, there are strengths, weaknesses, opportunities, and threats that must be considered and addressed.

Strengths:

Diabetes is a major public health issue that is having tremendous impact on the health, well-being, and productivity of the civilian and military populations of the U.S. The comprehensive approaches to prevention and treatment being used in this project target not only physiological basis of the illness but also its behavioral and lifestyle antecedents and determinants, integrating interventions into a comprehensive framework. The mission and vision are consistent with national and statewide initiatives (particularly those in Pennsylvania and Texas), offering a "laboratory" to demonstrate how these goals can be achieved.

The unique collaboration between the civilian and military sectors provides an opportunity to assess similarities and differences in deployment of programming in very varied geographic and demographic settings, allowing interventions to be tailored to best meet the needs of individual patients and special populations. In addition, the presence of considerable funding over multiple years supports both the breadth and depth of project, permitting multiple interventions to be tested and evaluated on a large scale, with longitudinal refinement and improvement.

We are building on considerable academic and clinical expertise and experience within UPMC, the University of Pittsburgh, and the U.S. military. The domain experts are internationally renowned for their academic work related to diabetes prevention and treatment and can draw on colleagues in academic institutions and professional associations across the world to provide guidance

and consultation to the project. Considerable resources are being dedicated to rigorous evaluation of project initiatives in order to produce results and knowledge that can be disseminated in the academic literature and critically assessed by researchers, policy makers, public health leaders, and clinical delivery systems.

Our efforts are valued and heavily endorsed by the leadership of the partnering organizations (UPMC, the University of Pittsburgh, and the military), recognizing that they have a responsibility to make the project successful. The populations served by all of these stakeholders stand to benefit from our efforts. Since 1994, we have established working relationships among the participating organizations that foster regular communication, oversight, and strategic direction.

Weaknesses:

Given the paucity of existing comprehensive and generalized models for diabetes prevention and treatment, this project is breaking new ground. Although we are drawing on the best available evidence from the literature and experience of other clinical delivery systems, the interventions being deployed must be evaluated to determine effectiveness, transferability, and cost-effectiveness. Definitive outcomes in terms of prevention of disease, improvement in clinical outcomes, and delay or prevention of complications may not be recognizable for a considerable period time that surpasses the project period, due to the prolonged natural history of diabetes. In addition, the lack of coherent health policy in the United States, it is unclear whether future third party reimbursement will support the programs being developed.

The procurement of funds on a year-to-year basis, through the appropriations process, creates a level of instability, with lack of assuredness about the length or amount of support. The need to write proposals and consummate contracts annually consumes a considerable amount of time and effort for both funding agencies and recipients, with the potential to detract from focus on programmatic initiatives. The project has also become much more complex in view of programming that spans multiple project years. With increased cumulative levels of funding, requirements, such as second level review during contracting have also been required and increasing effort must be devoted to generating comprehensive programmatic and financial reports.

This large and complex project requires considerable infrastructure that serves the needs of the military and civilian components and assures that deliverables are met. As the project grows, the level and nature of administrative support must continuously be examined and modified. Resources for this infrastructure must be used efficiently, in order to assure that sufficient funds are available to support programming. Recruitment and retention of qualified candidates for both administrative and programmatic functions can be very challenging, given the limited project period and funding of these positions on “soft” money. There has also been significant turnover among military personnel due to the war in Iraq and retirement, requiring building of new relationships and redefinition of roles. The decentralized nature of the project is inherently problematic in terms of ability to maintain and cultivate partnerships, develop effective channels of communication, and provide administrative support over great distances. Conduct of the program is dependent on access to requisite resources (such as information technology) and conformance with local regulatory processes (such as IRB approval) within partnering organizations which can be extremely challenging and create significant delays.

Opportunities:

This project represents a unique opportunity to establish new models for preventing and treating diabetes, through the creation of partnerships among domain experts as well as those who provide care. There will be steady expansion of programming into additional geographic sites and populations. It is also anticipated that relationships will be strengthened with professional organizations, third party payers, and statewide diabetes initiatives to assure alignment of project goals with environmental trends, public policy, and emerging financing mechanisms. Demonstrated cost-effectiveness of project initiatives can result in improved support for preventive and treatment interventions in military and civilian populations. The results of this project can not only create new models for prevention and treatment of diabetes but also generalize to improvements in the way we approach all chronic illness.

This project has the potential to significantly improve professional standards and the quality of care. Through expansion of certification and recognition by national associations to local sites caring for military and civilian populations, communities and remote military bases can gain access to benchmarked process and outcomes measures, and interact with colleagues from across the country. Based on results of project evaluation and assessment of the literature, protocols and guidelines can be produced, forming a basis on which to guide and assess the quality of care in diverse settings. The development of centers of excellence will provide evidence-based programs for prevention and treatment that can be easily accessed by patients and providers. Innovative methods will be developed to disseminate expertise, through the used of centralized interpretation of remotely obtained diagnostic tests (such as retinal screenings), tele-consultation, and assessments provided by designated assessment teams. There is great potential for the project to capitalize on advances in information technology. Given the increased emphasis on use of electronic health records in both inpatient and outpatient settings, process and outcomes data will become more readily available to aid in improving care at the local and national levels. Improved modalities for communication will foster collaboration among care sites.

The development for inter-service models of care delivery within the military will foster deployment of the project in increasing numbers of settings. In addition, there will be enhanced access to expertise within the military and the opportunity to gain more insight into the unique aspects of this population and care setting. The project has the potential to improve the physical qualifications of new recruits, enhance performance and productivity of active duty personnel, and improve the health of beneficiaries, retirees, and veterans.

It is hoped that this project will provide new metrics for evaluating the quality, cost-effectiveness and accessibility of interventions to prevent and treat of diabetes and other chronic diseases. In addition, outcomes will also inform the national research agenda.

Threats:

This is a large and ambitious project that will require several more years to achieve the desired results. This strategic plan is predicated on procuring FY ’09 and FY ’10 appropriations. In view of the evolving political environment, it is unclear whether the current processes and procedures for appropriations will continue. Although alternative funding sources, such as federal grant programs, foundations, or industry, may be made available; it is unlikely that financial support at the level

provided in prior years would be achieved. In addition, there has traditionally be less funding for this type of translational research than for more basic scientific investigation.

As mentioned previously, the state of health policy in the United States is in great flux. Facing increasing health care costs, a large percentage of un- and under-insured, and an aging population, there will certainly be major changes in financing mechanisms and healthcare priorities. While we see this as a potential opportunity for the kinds of prevention and treatment strategies being developed in this project, we also perceive the uncertainty in U.S. health policy as a likely threat, given the potential emphasis for short-term monetary savings and need to provide a more basic package of services to an expanded population. There are similar issues in the military population, given the demographics of the veteran population and great demands for care of the returning war wounded.

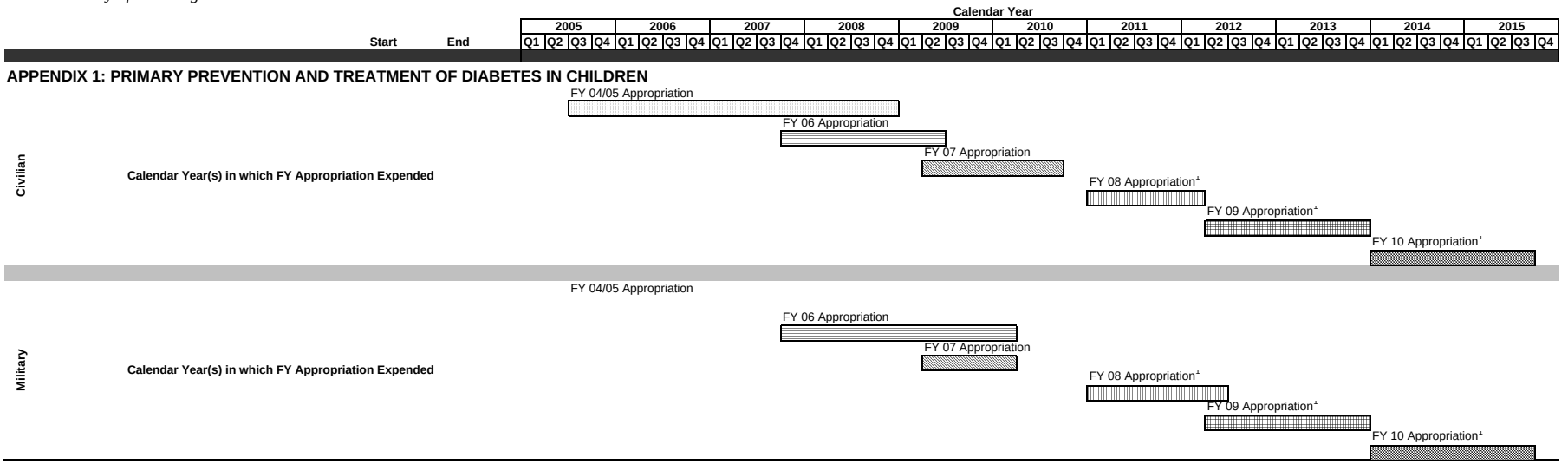
New models of care are going to require a different complement of health care workers and programs that target primary prevention of disease. Within the last ten years, there has been a steady decline of physicians going into primary care fields and reimbursement and state licensure requirements have limited the supply of advanced practice professionals. If the initiatives of this project prove to be successful, there will be a great demand for new types of personnel, with a resulting shortage of qualified workers (particularly in areas that are currently under-served) until education and training programs can implement new curricula and expand their student body. There may also be a need for professional organizations to establish new types of certifications and for licensing bodies to redefine scope of practice, which may be met with question or some opposition.

X. Measures of Achievement:

A variety of measures will be used to assess parameters associated with project outcomes, including:

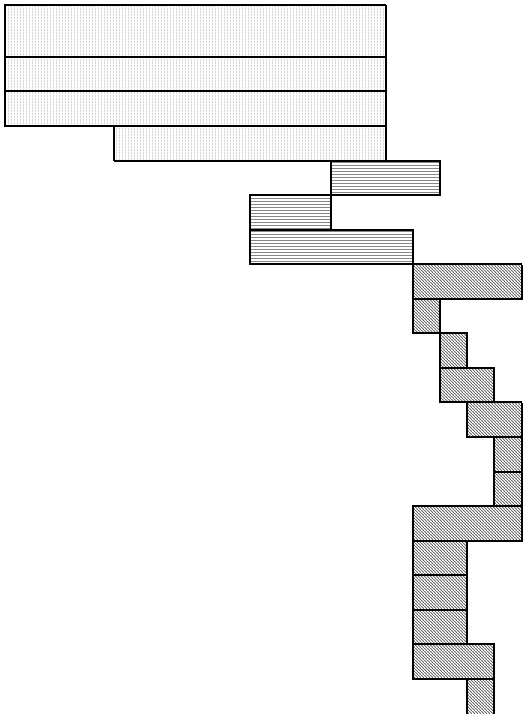
- *Programmatic effectiveness:* Measures include achievement of stated deliverables, budgetary goals, successful contracting, compliance with regulatory requirements, and administrative effectiveness.
- *Reach*: Number of participating sites, number of patients enrolled, diversity of geographic sites, diversity of populations served (based on age, gender, race, ethnicity, civilian vs. military, and other demographics)
- *Clinical outcomes:* Outcomes and process measures
- *Financial impact:* Cost-effectiveness of programmatic initiatives, potential for third party reimbursement
- *Academic impact:* Numbers of presentations and publications, interaction with national and international organizations, impact on research agendas
- *Sustainability of programming:* Continuation of programming at the conclusion of funding.

APPENDIX 1: PRIMARY PREVENTION AND TREATMENT OF DIABETES IN CHILDREN



Develop and implement clinical programs for management of obesity and prevention of diabetes

	Start	End
Civilian		
Implement and expand the weight management center at Children's Hospital, including development and implementation of care protocols	Complete	
Implement the HEROES program	Complete	
Outreach to community sites in western PA	Complete	
Evaluate clinical processes and protocols	1-Jul-06	31-Jul-08
Expand services and enrollment at the weight management center	1-Jul-08	30-Jun-09
Enhance the HEROES program by introducing additional elements	1-Oct-07	30-Jun-08
Evaluate the clinical programs at CHP	1-Oct-07	31-Mar-09
Evaluate the impact of an exercise training program	1-Apr-09	31-Mar-10
Recruit subjects (BMI ≥ 95th percentile for age/sex) to participate in 3-month intervention	1-Apr-09	30-Jun-09
Conduct pre-intervention evaluations	1-Jul-09	31-Jul-09
Implement exercise and/or diet interventions	1-Aug-09	31-Oct-09
Conduct post-intervention evaluations	1-Nov-09	31-Jan-10
Perform data analysis	1-Jan-10	28-Feb-10
Prepare final report on project	1-Feb-10	31-Mar-10
Further refine the clinic-based lifestyle management program to prepare for national adoption	1-Apr-09	31-Mar-10
Collect patient cycle time data	1-Apr-09	30-Sep-09
Collect patient satisfaction results	1-Apr-09	30-Sep-09
Track clinical vs administrative hours WMWC staff	1-Apr-09	30-Sep-09
Research and determine third party insurance reimbursement for individual services	1-Apr-09	30-Nov-09
Analyze data	1-Oct-09	30-Nov-09



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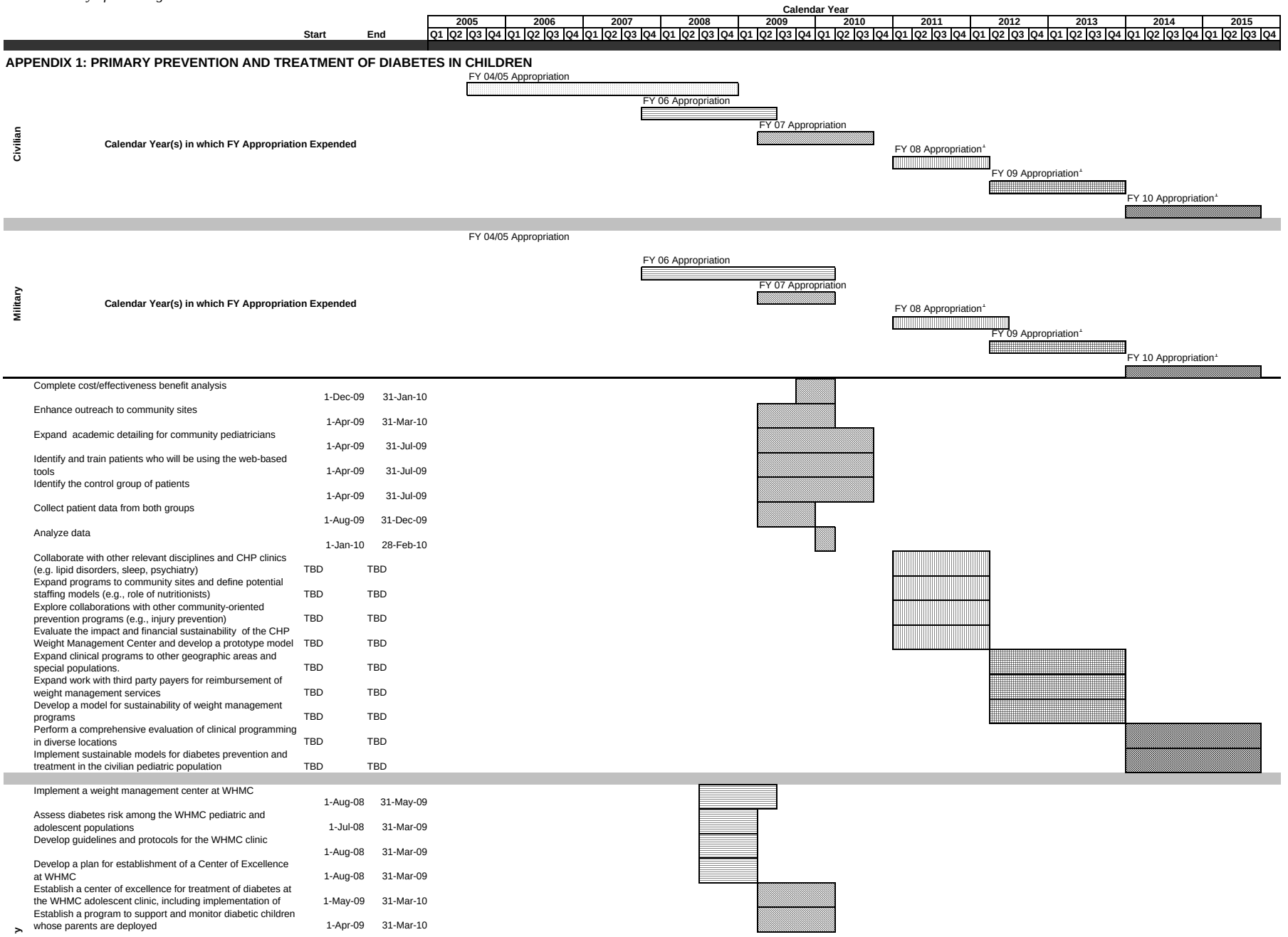
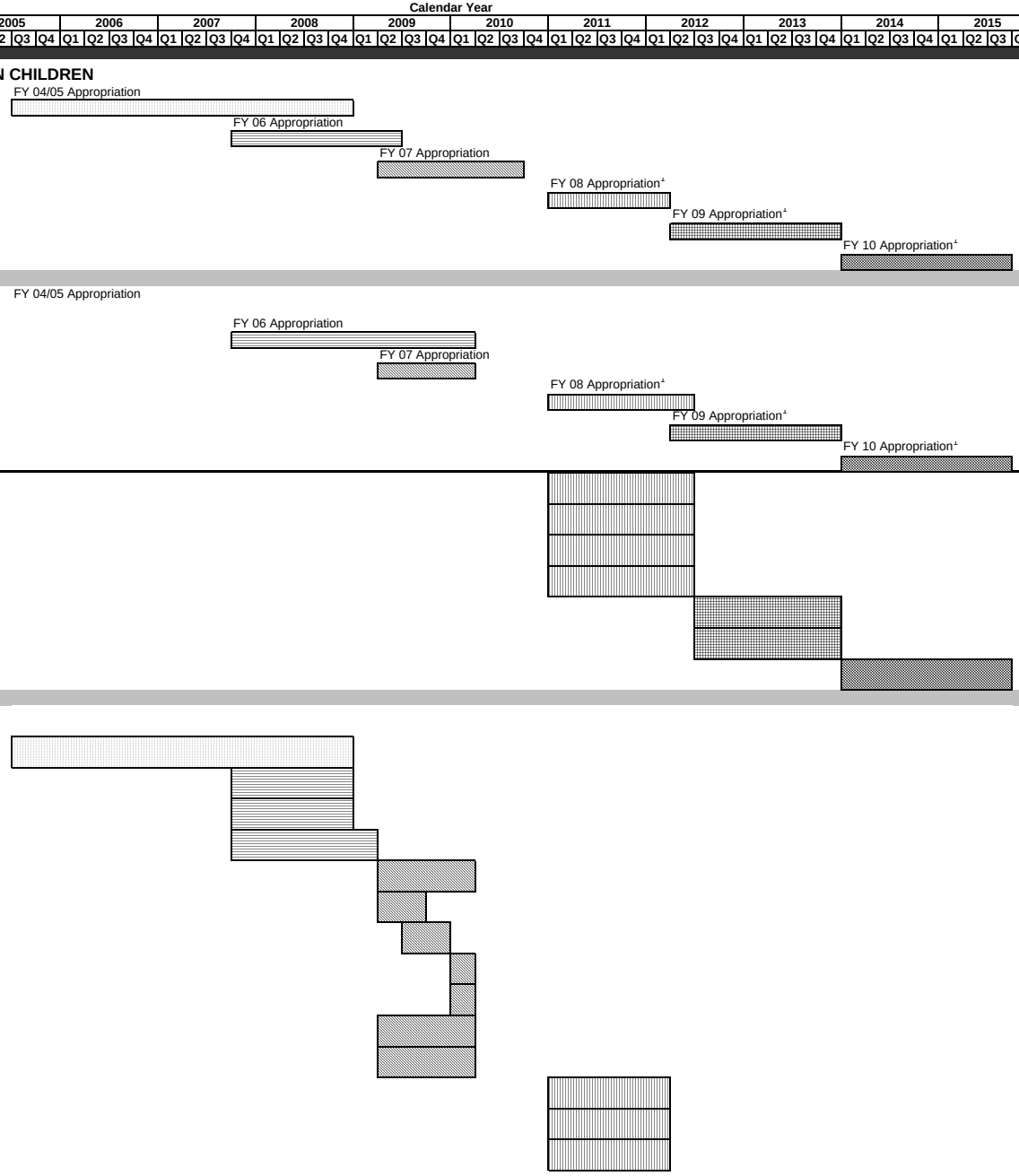


APPENDIX 1: PRIMARY PREVENTION AND TREATMENT OF DIABETES IN CHILDREN

		Start	End
Civilian	**Calendar Year(s) in which FY Appropriation Expended**		
Military	**Calendar Year(s) in which FY Appropriation Expended**		
Military	Expand the scope of activities of the Center of Excellence for prevention and treatment of diabetes at other military	TBD	TBD
	Enhance activities of the lifestyle management program	TBD	TBD
	Support the treatment of diabetes in military pediatric primary care clinics in San Antonio	TBD	TBD
	Develop data systems to assess the quality of preventive and medical care in outpatient clinics	TBD	TBD
	Expand the scope of activities of the Center of Excellence to military bases across the country: Ft. Polk, Ft. Riley, Keelser,	TBD	TBD
	Evaluate the impact of the lifestyle management program	TBD	TBD
	Implement sustainable clinical models for prevention and treatment of obesity among military dependents	TBD	TBD
	Develop and implement Web-based tools to support the management of obesity and prevention of diabetes		
	Develop and implement Healthy Plate	Complete	
	Develop and implement the weight management portal	1-Nov-07	30-Nov-08
	Integrate Healthy Plate into the portal	1-Nov-07	30-Nov-08
	Evaluate web tools in pilot deployments	1-Nov-07	31-Mar-09
	Evaluate the impact of web-based tools	1-Apr-09	31-Mar-10
	Identify the control group of patients	1-Apr-09	31-Jul-09
	Collect patient data from both groups	1-Aug-09	31-Dec-09
	Analyze the data	1-Jan-10	28-Feb-10
	Complete the final report on the intervention project	1-Mar-10	31-Mar-10
Civilian	Make tools available to increased number of community sites	1-Apr-09	31-Mar-10
	Identify and train patients who will be using the web-based tools	1-Apr-09	31-Mar-10
	Expand use of tools in Children's Hospital community practices	TBD	TBD
	Make tools accessible to at least one school district	TBD	TBD
	Evaluate effectiveness of the tools	TBD	TBD



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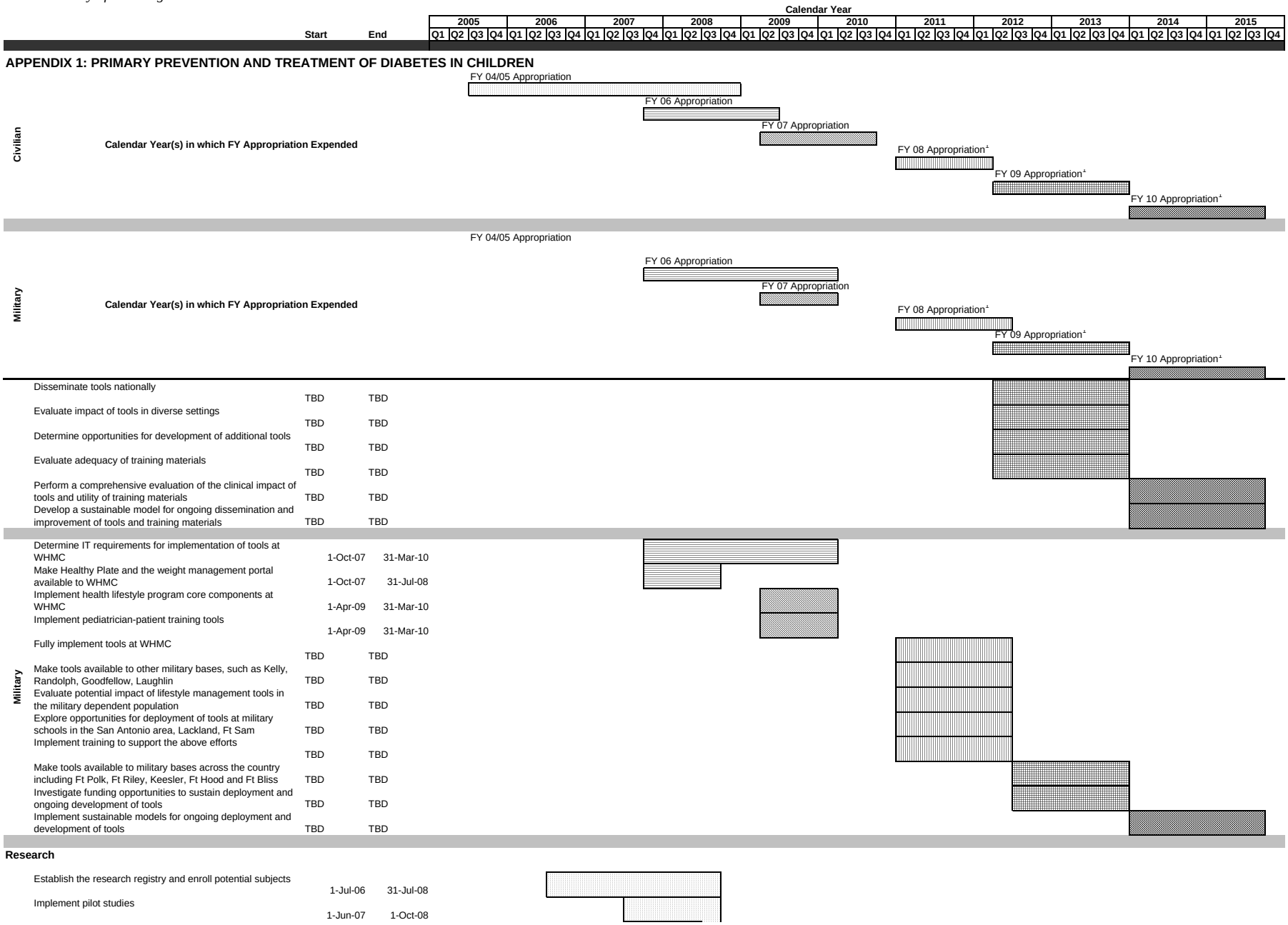

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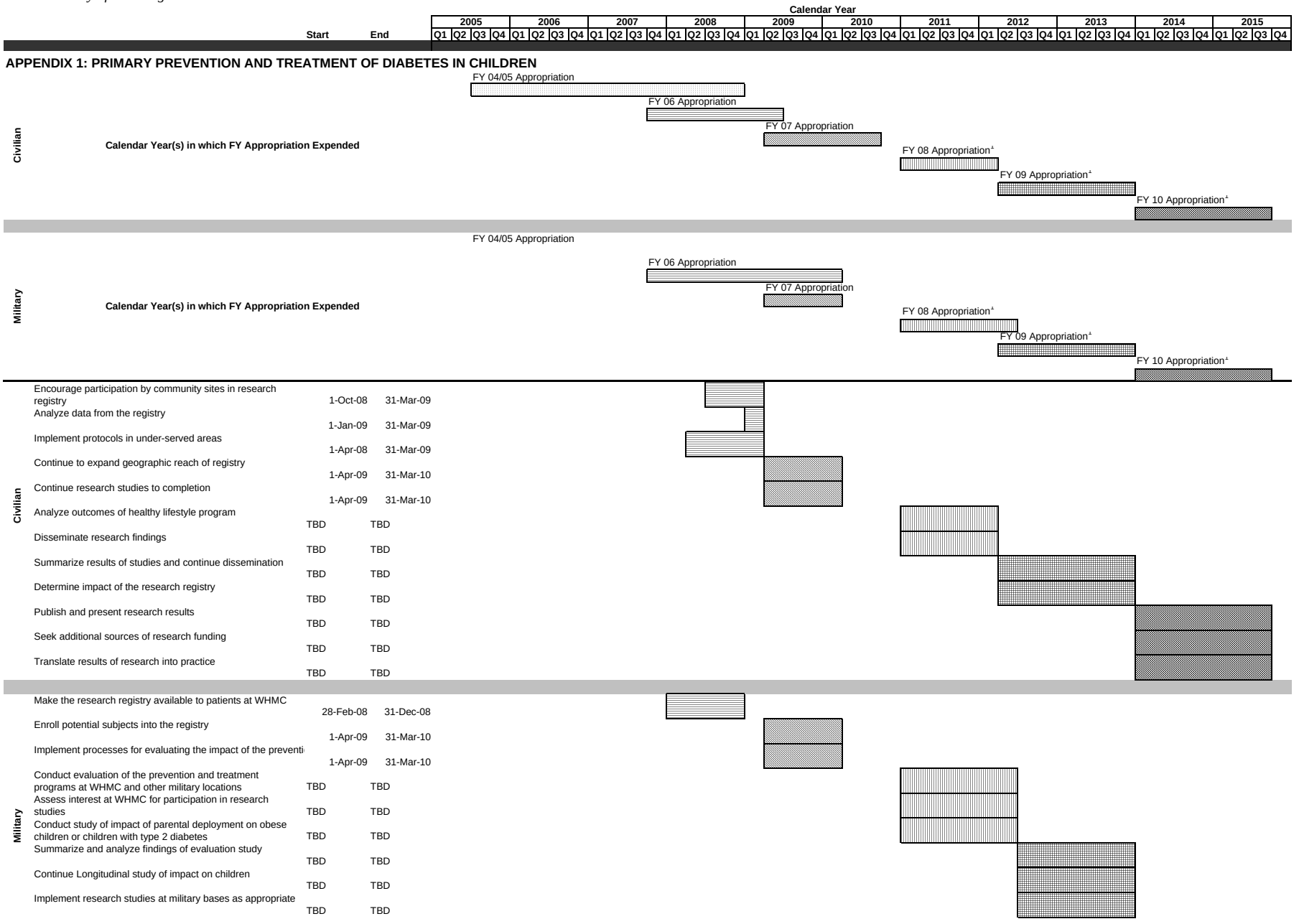

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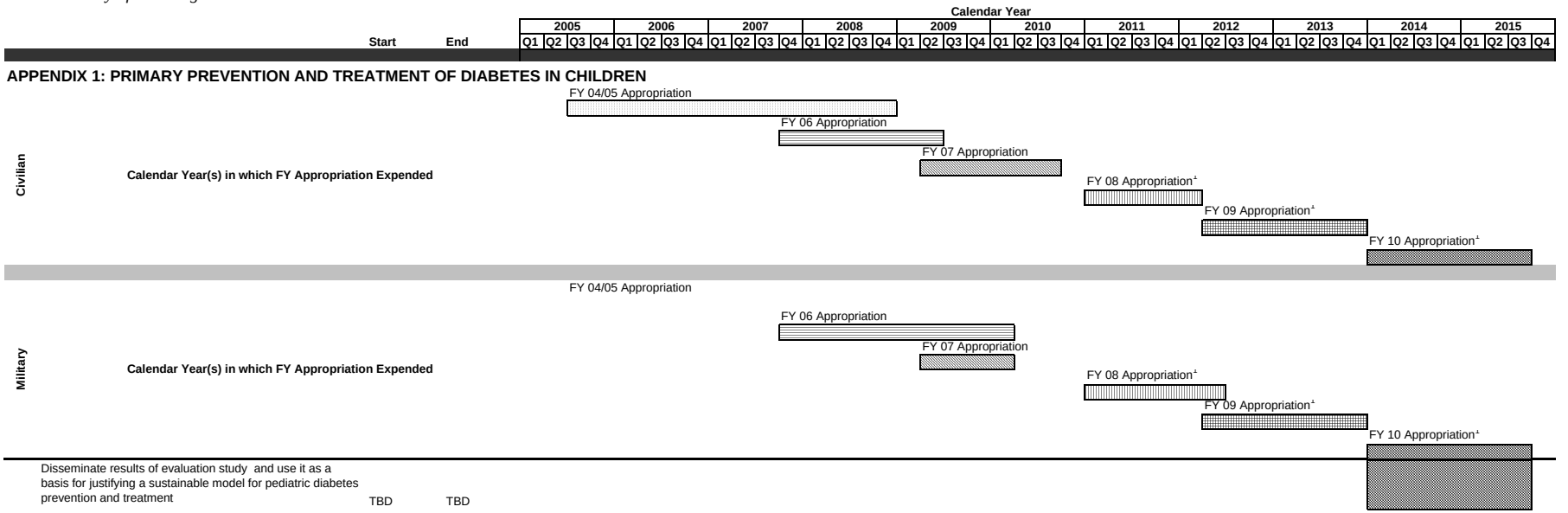

[1]Definitive Dates for each technical objective have not yet been determined for FY08, FY09, or FY10 funding. Shading is representative of expected Period of Performance

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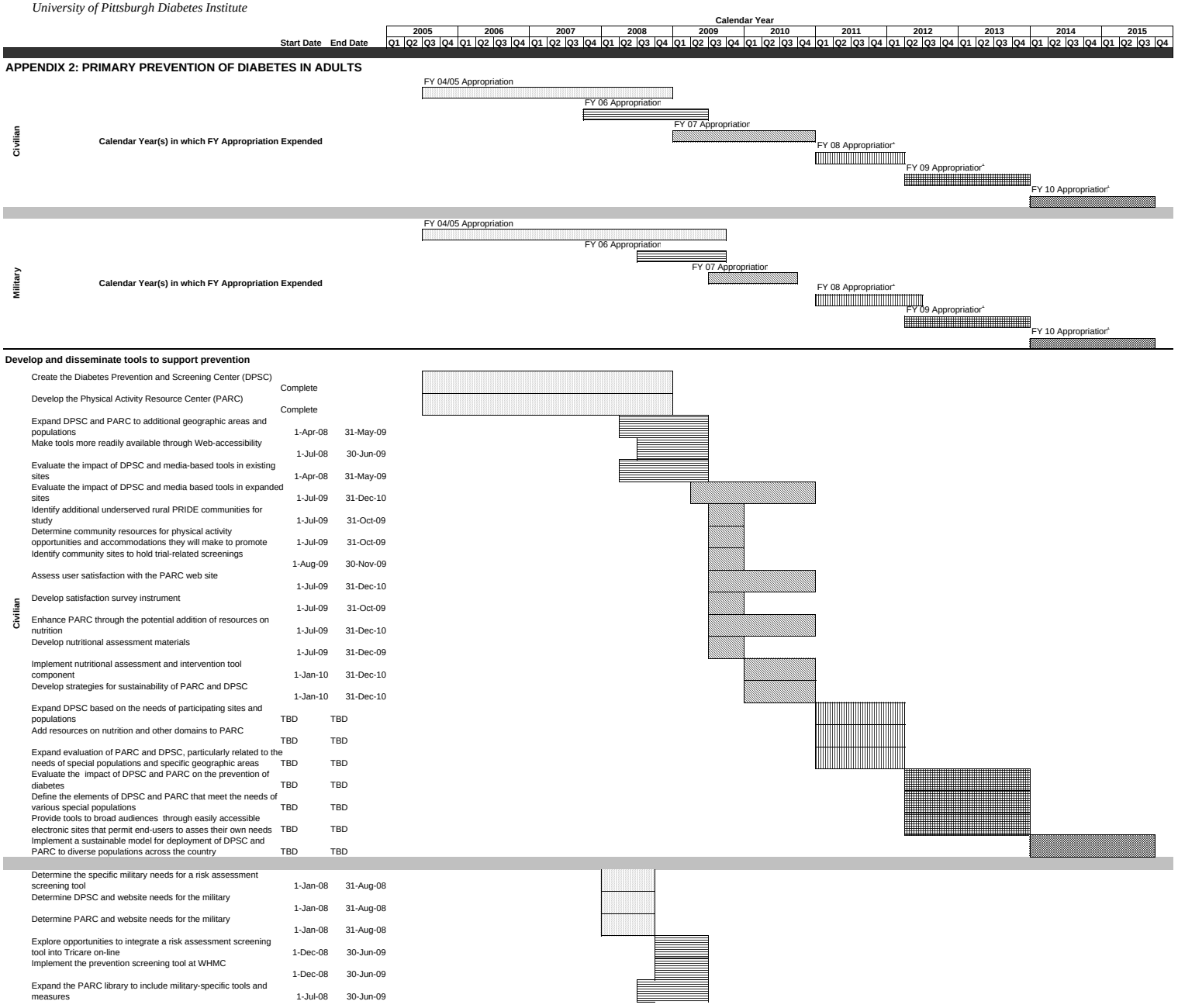

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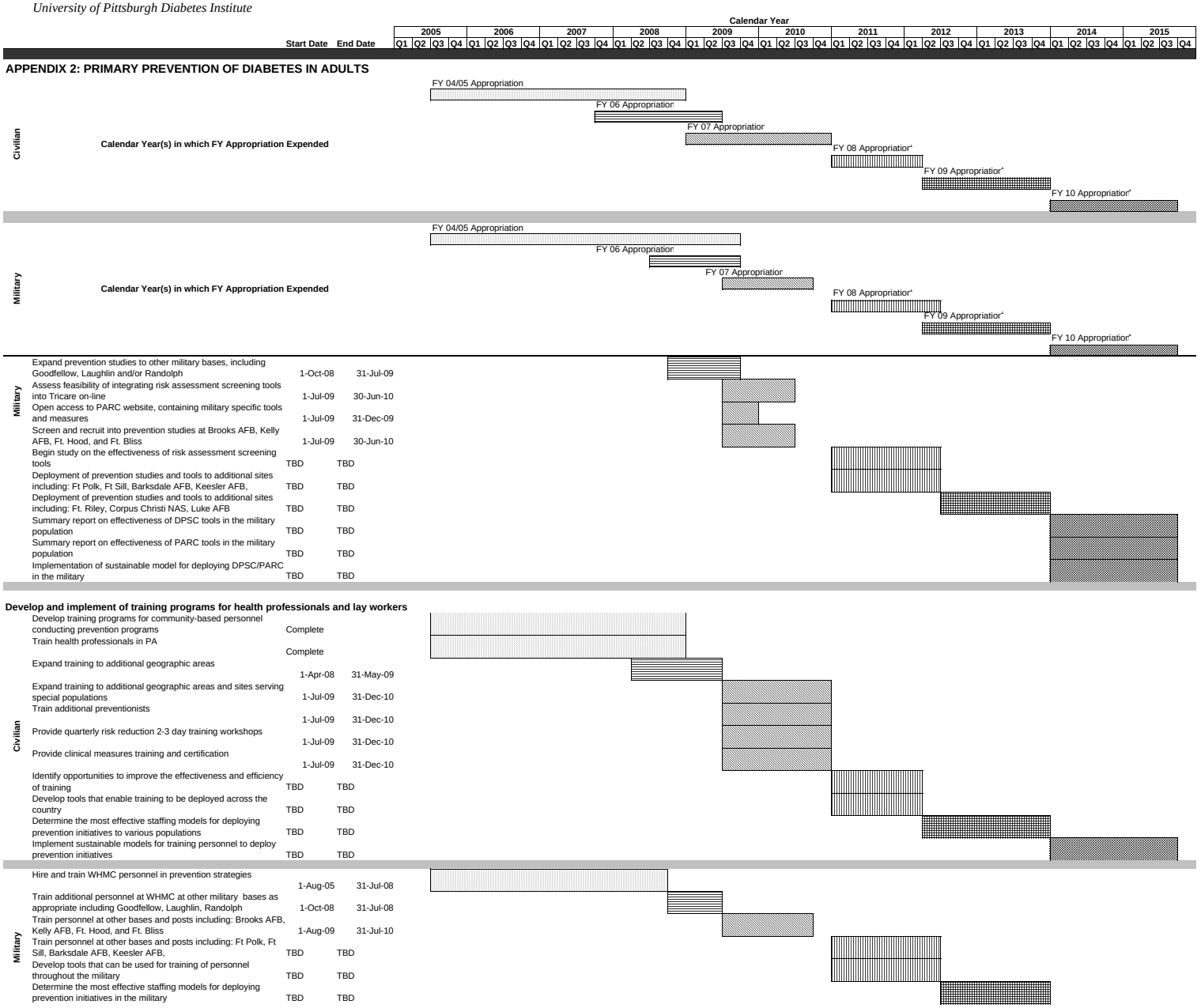
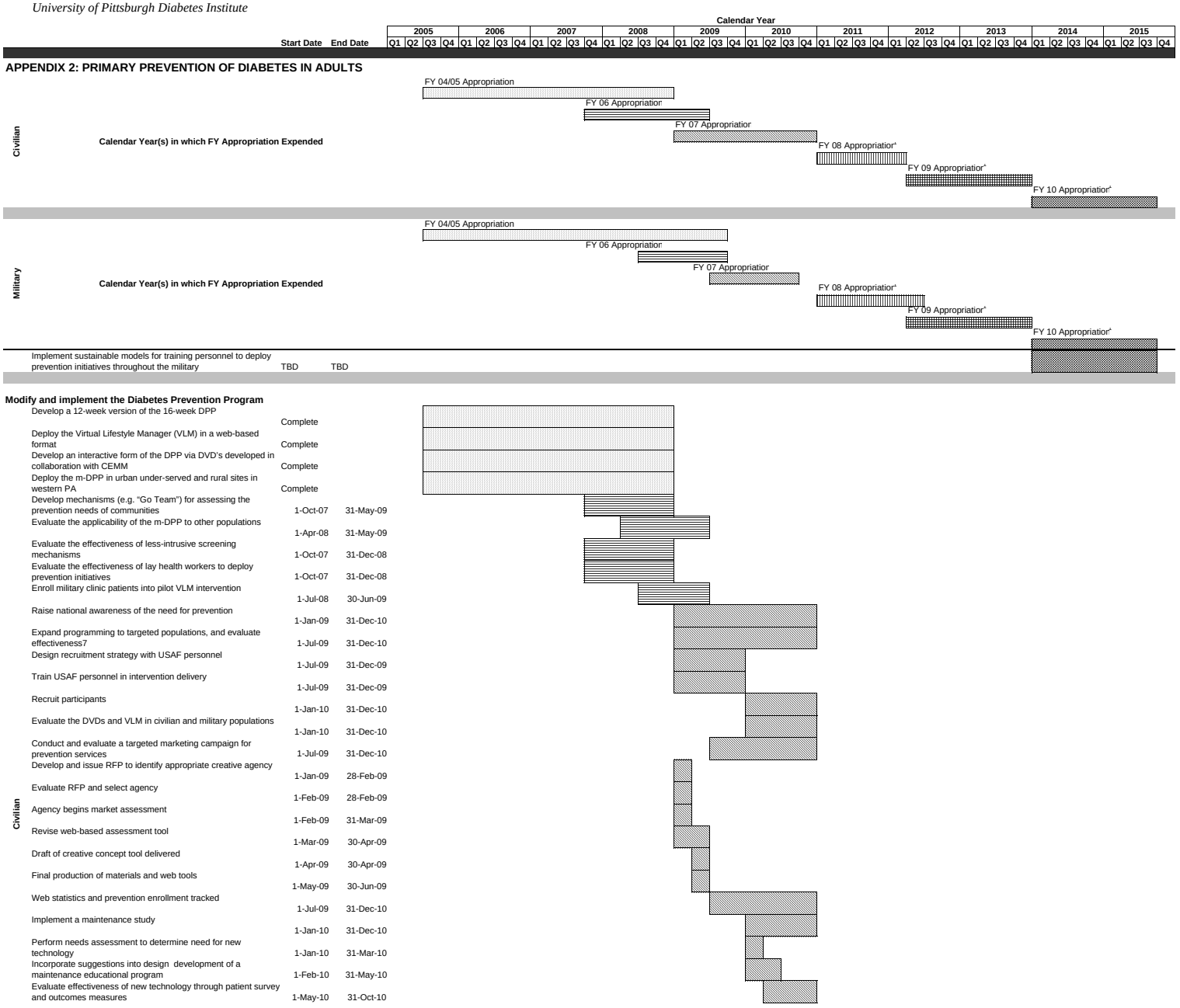
APPENDIX 2: PRIMARY PREVENTION OF DIABETES IN ADULTS




Calendar Year
2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015
Q1 Q2 Q3 Q4
Start Date End Date
APPENDIX 2: PRIMARY PREVENTION OF DIABETES IN ADULTS
Civilian
Calendar Year(s) in which FY Appropriation Expended
FY 04/05 Appropriation
FY 06 Appropriation
FY 07 Appropriation
FY 08 Appropriation[a]
FY 09 Appropriation[a]
FY 10 Appropriation[a]
Military
Calendar Year(s) in which FY Appropriation Expended
FY 04/05 Appropriation
FY 06 Appropriation
FY 07 Appropriation
FY 08 Appropriation[a]
FY 09 Appropriation[a]
FY 10 Appropriation[a]
Implement sustainable models for training personnel to deploy prevention initiatives throughout the military TBD TBD
Modify and implement the Diabetes Prevention Program
Develop a 12-week version of the 16-week DPP Complete
Deploy the Virtual Lifestyle Manager (VLM) in a web-based format Complete
Develop an interactive form of the DPP via DVD's developed in collaboration with CEMM Complete
Deploy the m-DPP in urban under-served and rural sites in western PA Complete
Develop mechanisms (e.g. "Go Team") for assessing the prevention needs of communities 1-Oct-07 31-May-09
Evaluate the applicability of the m-DPP to other populations 1-Apr-08 31-May-09
Evaluate the effectiveness of less-intrusive screening mechanisms 1-Oct-07 31-Dec-08
Evaluate the effectiveness of lay health workers to deploy prevention initiatives 1-Oct-07 31-Dec-08
Enroll military clinic patients into pilot VLM intervention 1-Jul-08 30-Jun-09
Raise national awareness of the need for prevention 1-Jan-09 31-Dec-10
Expand programming to targeted populations, and evaluate effectiveness7 1-Jul-09 31-Dec-10
Design recruitment strategy with USAF personnel 1-Jul-09 31-Dec-09
Train USAF personnel in intervention delivery 1-Jul-09 31-Dec-09
Recruit participants 1-Jan-10 31-Dec-10
Evaluate the DVDs and VLM in civilian and military populations 1-Jan-10 31-Dec-10
Conduct and evaluate a targeted marketing campaign for prevention services 1-Jul-09 31-Dec-10
Develop and issue RFP to identify appropriate creative agency 1-Jan-09 28-Feb-09
Evaluate RFP and select agency 1-Feb-09 28-Feb-09
Agency begins market assessment 1-Feb-09 31-Mar-09
Revise web-based assessment tool 1-Mar-09 30-Apr-09
Draft of creative concept tool delivered 1-Apr-09 30-Apr-09
Final production of materials and web tools 1-May-09 30-Jun-09
Web statistics and prevention enrollment tracked 1-Jul-09 31-Dec-10
Implement a maintenance study 1-Jan-10 31-Dec-10
Perform needs assessment to determine need for new technology 1-Jan-10 31-Mar-10
Incorporate suggestions into design development of a maintenance educational program 1-Feb-10 31-May-10
Evaluate effectiveness of new technology through patient survey and outcomes measures 1-May-10 31-Oct-10
Civilian

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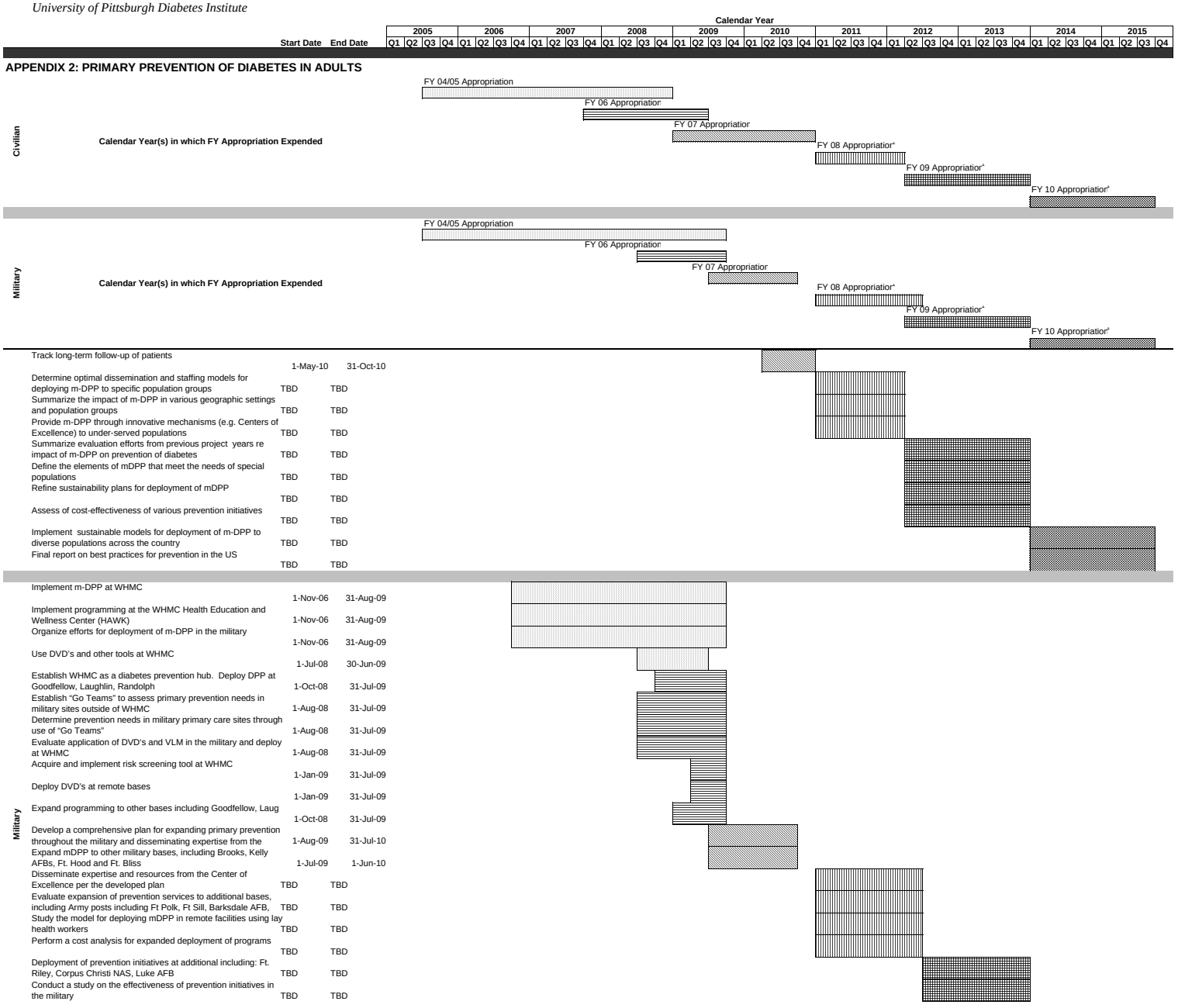
APPENDIX 2: PRIMARY PREVENTION OF DIABETES IN ADULTS



		Start Date	End Date
Civilian	Track long-term follow-up of patients	1-May-10	31-Oct-10
	Determine optimal dissemination and staffing models for deploying m-DPP to specific population groups	TBD	TBD
	Summarize the impact of m-DPP in various geographic settings and population groups	TBD	TBD
	Provide m-DPP through innovative mechanisms (e.g. Centers of Excellence) to under-served populations	TBD	TBD
	Summarize evaluation efforts from previous project years re impact of m-DPP on prevention of diabetes	TBD	TBD
	Define the elements of mDPP that meet the needs of special populations	TBD	TBD
	Refine sustainability plans for deployment of mDPP	TBD	TBD
	Assess of cost-effectiveness of various prevention initiatives	TBD	TBD
	Implement sustainable models for deployment of m-DPP to diverse populations across the country	TBD	TBD
	Final report on best practices for prevention in the US	TBD	TBD
Military	Implement m-DPP at WHMC	1-Nov-06	31-Aug-09
	Implement programming at the WHMC Health Education and Wellness Center (HAWK)	1-Nov-06	31-Aug-09
	Organize efforts for deployment of m-DPP in the military	1-Nov-06	31-Aug-09
	Use DVD's and other tools at WHMC	1-Jul-08	30-Jun-09
	Establish WHMC as a diabetes prevention hub. Deploy DPP at Goodfellow, Laughlin, Randolph	1-Oct-08	31-Jul-09
	Establish "Go Teams" to assess primary prevention needs in military sites outside of WHMC	1-Aug-08	31-Jul-09
	Determine prevention needs in military primary care sites through use of "Go Teams"	1-Aug-08	31-Jul-09
	Evaluate application of DVD's and VLM in the military and deploy at WHMC	1-Aug-08	31-Jul-09
	Acquire and implement risk screening tool at WHMC	1-Jan-09	31-Jul-09
	Deploy DVD's at remote bases	1-Jan-09	31-Jul-09
	Expand programming to other bases including Goodfellow, Laug	1-Oct-08	31-Jul-09
	Develop a comprehensive plan for expanding primary prevention throughout the military and disseminating expertise from the	1-Aug-09	31-Jul-10
	Expand mDPP to other military bases, including Brooks, Kelly AFBs, Ft. Hood and Ft. Bliss	1-Jul-09	1-Jun-10
	Disseminate expertise and resources from the Center of Excellence per the developed plan	TBD	TBD
	Evaluate expansion of prevention services to additional bases, including Army posts including Ft Polk, Ft Sill, Barksdale AFB,	TBD	TBD
	Study the model for deploying mDPP in remote facilities using lay health workers	TBD	TBD
	Perform a cost analysis for expanded deployment of programs	TBD	TBD
	Deployment of prevention initiatives at additional including: Ft. Riley, Corpus Christi NAS, Luke AFB	TBD	TBD
	Conduct a study on the effectiveness of prevention initiatives in the military	TBD	TBD

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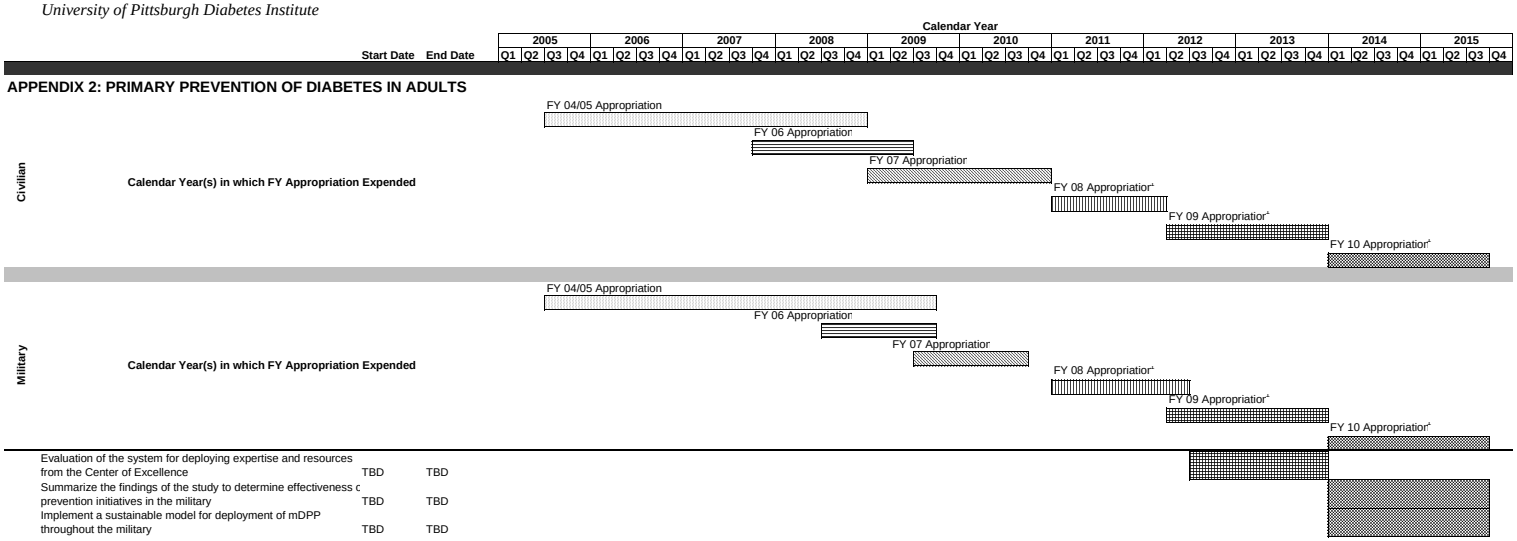
APPENDIX 2: PRIMARY PREVENTION OF DIABETES IN ADULTS



	Start Date	End Date
Evaluation of the system for deploying expertise and resources from the Center of Excellence	TBD	TBD
Summarize the findings of the study to determine effectiveness o prevention initiatives in the military	TBD	TBD
Implement a sustainable model for deployment of mDPP throughout the military	TBD	TBD

[1]Definitive Dates for each technical objective have not yet been determined for FY08, FY09, or FY10 funding. Shading is representative of expected Period of Performance

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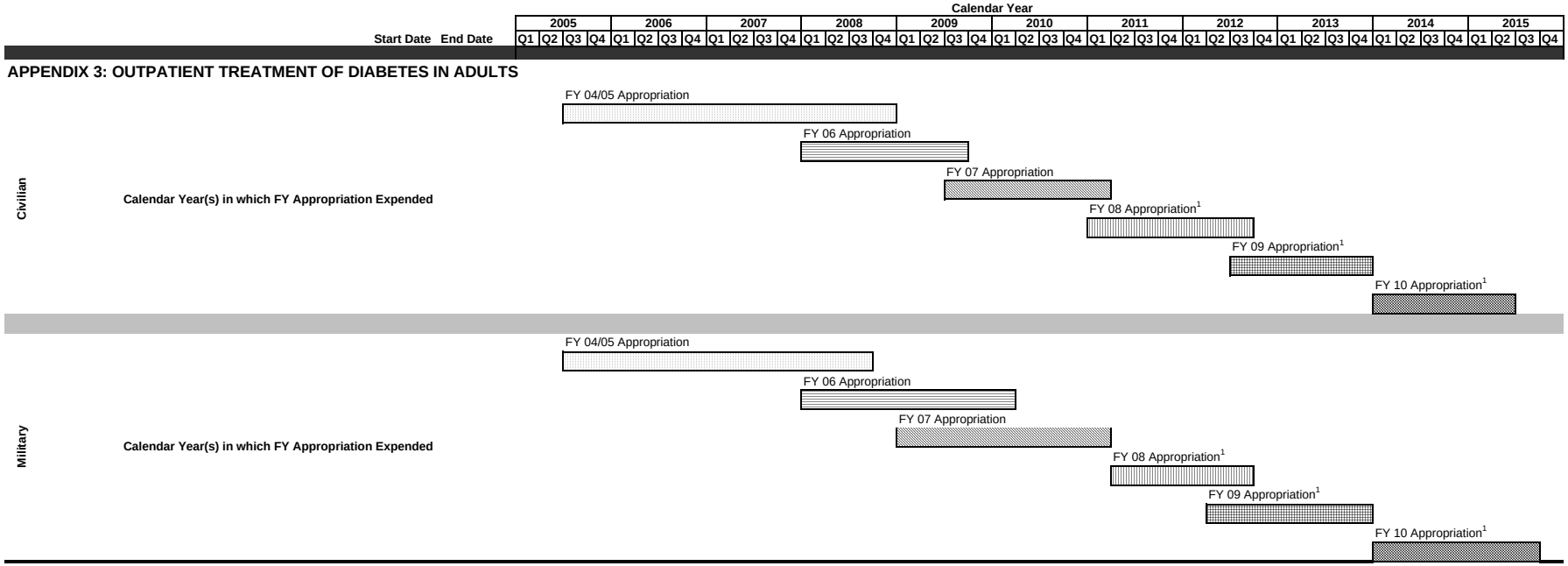
APPENDIX 3: OUTPATIENT TREATMENT OF DIABETES IN ADULTS



	Start Date	End Date
Implement the Chronic Care Model		
Conceptualize the application of the CCM to diabetes care	Complete	
Implement the CCM at UPMC sites	Complete	
Establish the PRIDE network in rural PA sites	Complete	
Implement the CCM in the PRIDE sites	Complete	
Evaluate processes and outcomes in PRIDE sites to identify successes and opportunities for improvement	1-Jan-08	31-Jul-09
Develop innovative models for provision of specialty services in PRIDE sites	1-Jan-08	31-Jul-09
Align initiatives in PRIDE sites with the PA Diabetes Plan	1-Sep-08	30-Sep-09
Using data from the previous years' evaluation, extend the CCM to additional rural primary care practices in western PA	1-Aug-09	31-Jan-11
Identify 12 PCP practices in PRIDE communities	1-Aug-09	31-Oct-09
Design Qualitative implementation and instruments	1-Aug-09	30-Nov-09
Educate practices on menu selections of interventions	1-Oct-09	31-Dec-09
Evaluate the impact of innovative provisions of specialty services in primary care sites	1-Aug-09	31-Jan-11
Conduct focus groups with community physicians/office managers	1-Aug-09	31-Oct-09
Deploy practice coaches	1-Dec-09	28-Feb-10

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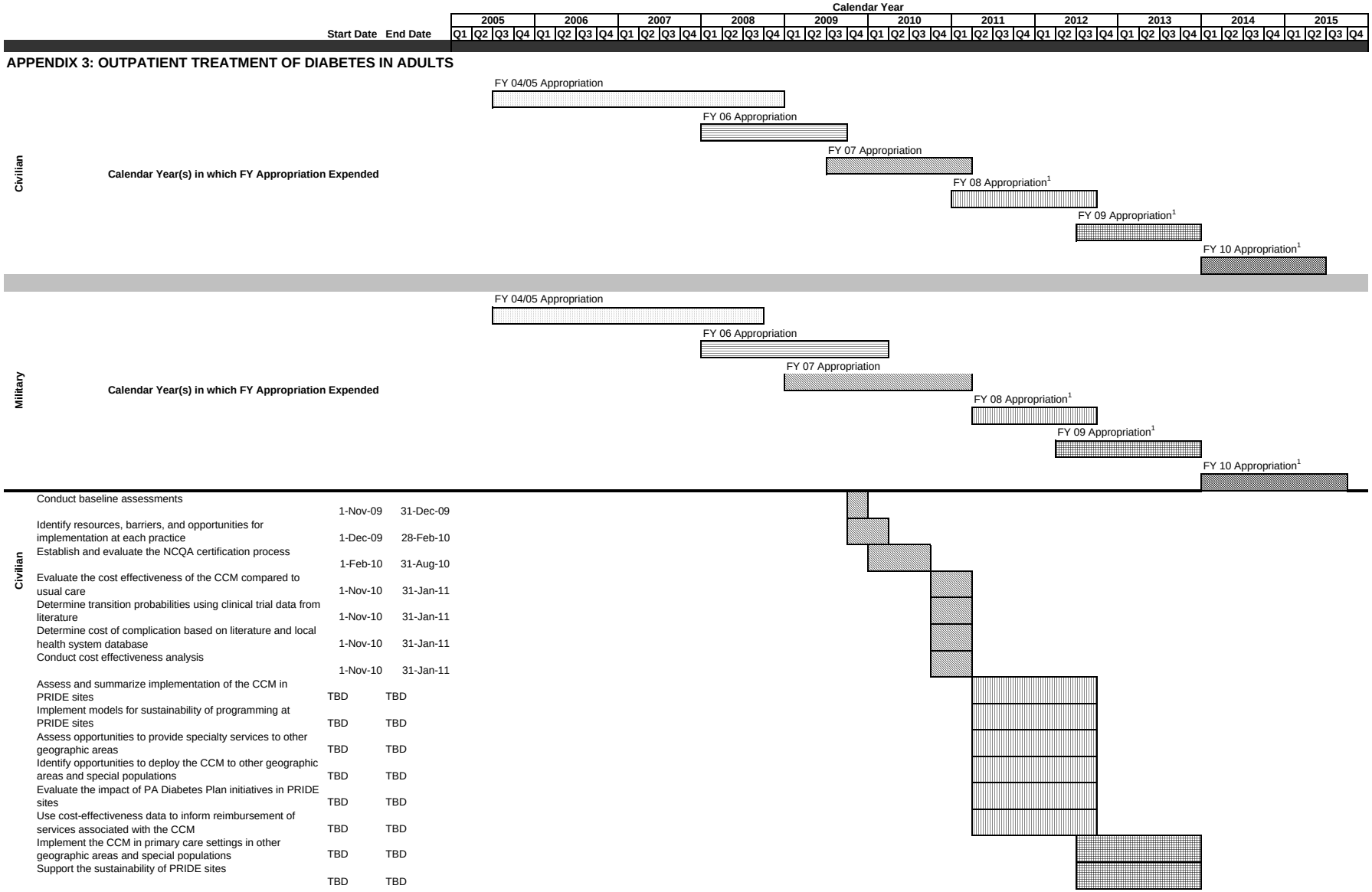

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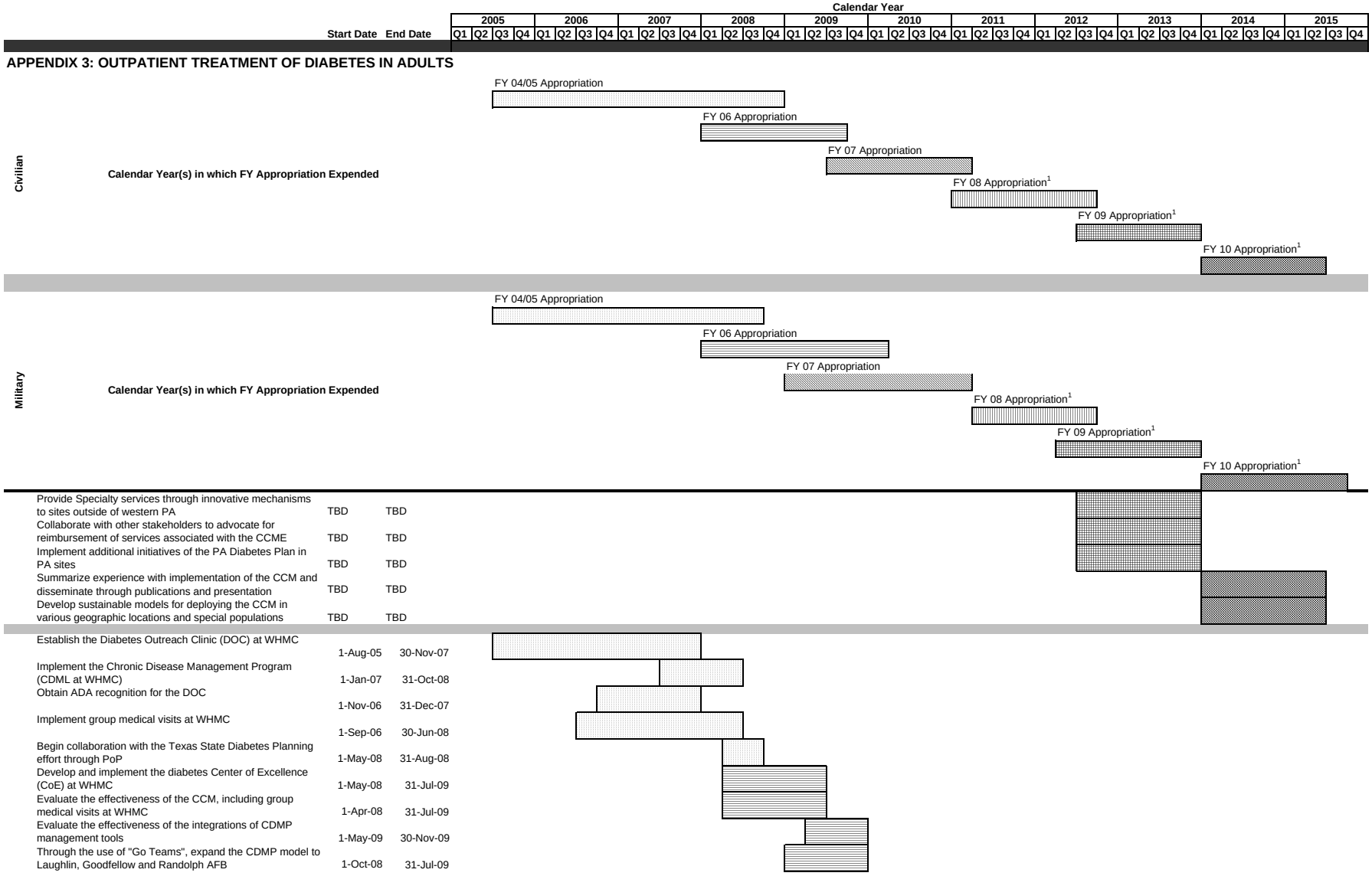

	Start Date	End Date
Provide Specialty services through innovative mechanisms to sites outside of western PA	TBD	TBD
Collaborate with other stakeholders to advocate for reimbursement of services associated with the CCME	TBD	TBD
Implement additional initiatives of the PA Diabetes Plan in PA sites	TBD	TBD
Summarize experience with implementation of the CCM and disseminate through publications and presentation	TBD	TBD
Develop sustainable models for deploying the CCM in various geographic locations and special populations	TBD	TBD
Establish the Diabetes Outreach Clinic (DOC) at WHMC	1-Aug-05	30-Nov-07
Implement the Chronic Disease Management Program (CDML at WHMC)	1-Jan-07	31-Oct-08
Obtain ADA recognition for the DOC	1-Nov-06	31-Dec-07
Implement group medical visits at WHMC	1-Sep-06	30-Jun-08
Begin collaboration with the Texas State Diabetes Planning effort through PoP	1-May-08	31-Aug-08
Develop and implement the diabetes Center of Excellence (CoE) at WHMC	1-May-08	31-Jul-09
Evaluate the effectiveness of the CCM, including group medical visits at WHMC	1-Apr-08	31-Jul-09
Evaluate the effectiveness of the integrations of CDMP management tools	1-May-09	30-Nov-09
Through the use of "Go Teams", expand the CDMP model to Laughlin, Goodfellow and Randolph AFB	1-Oct-08	31-Jul-09

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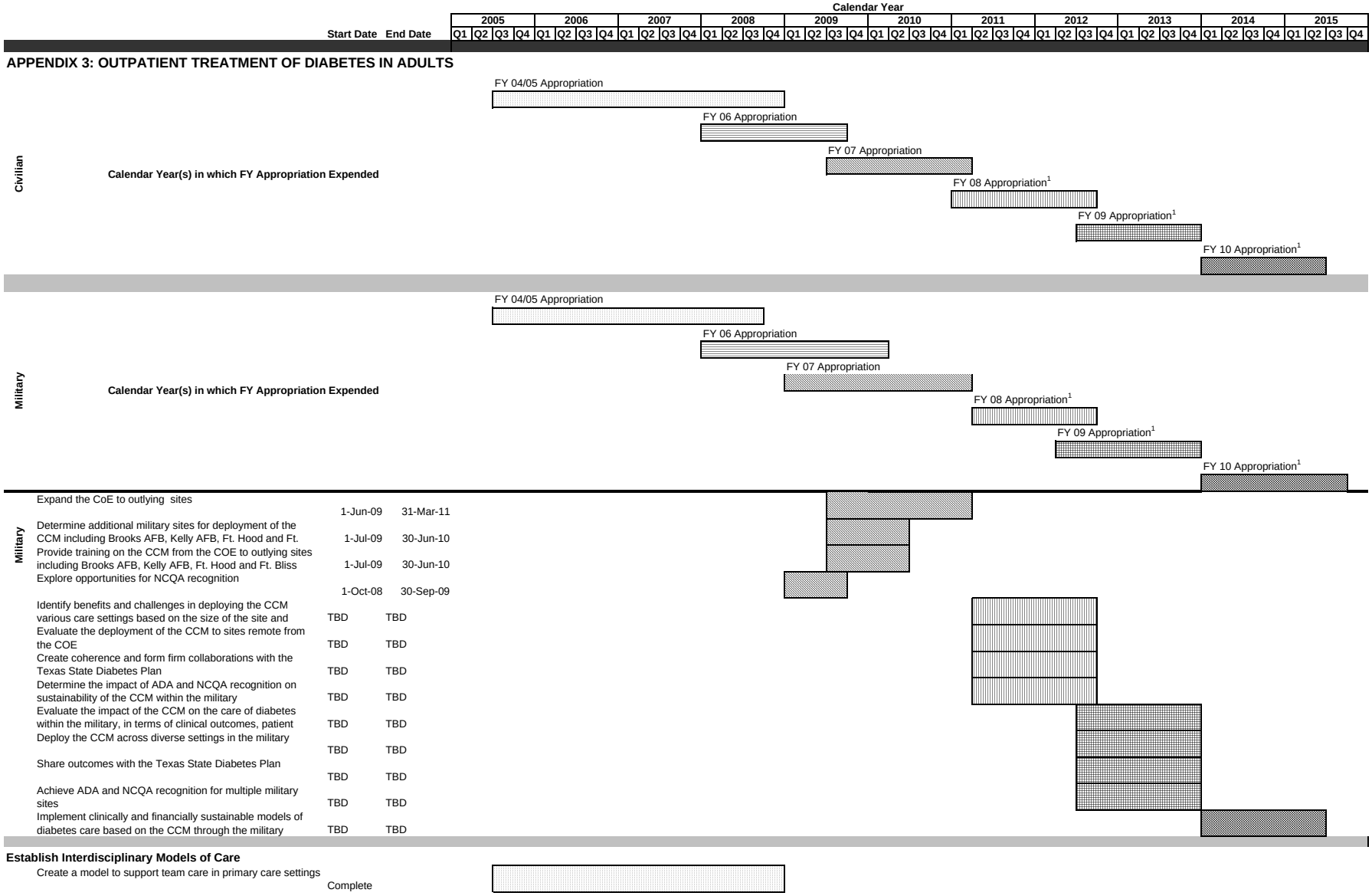

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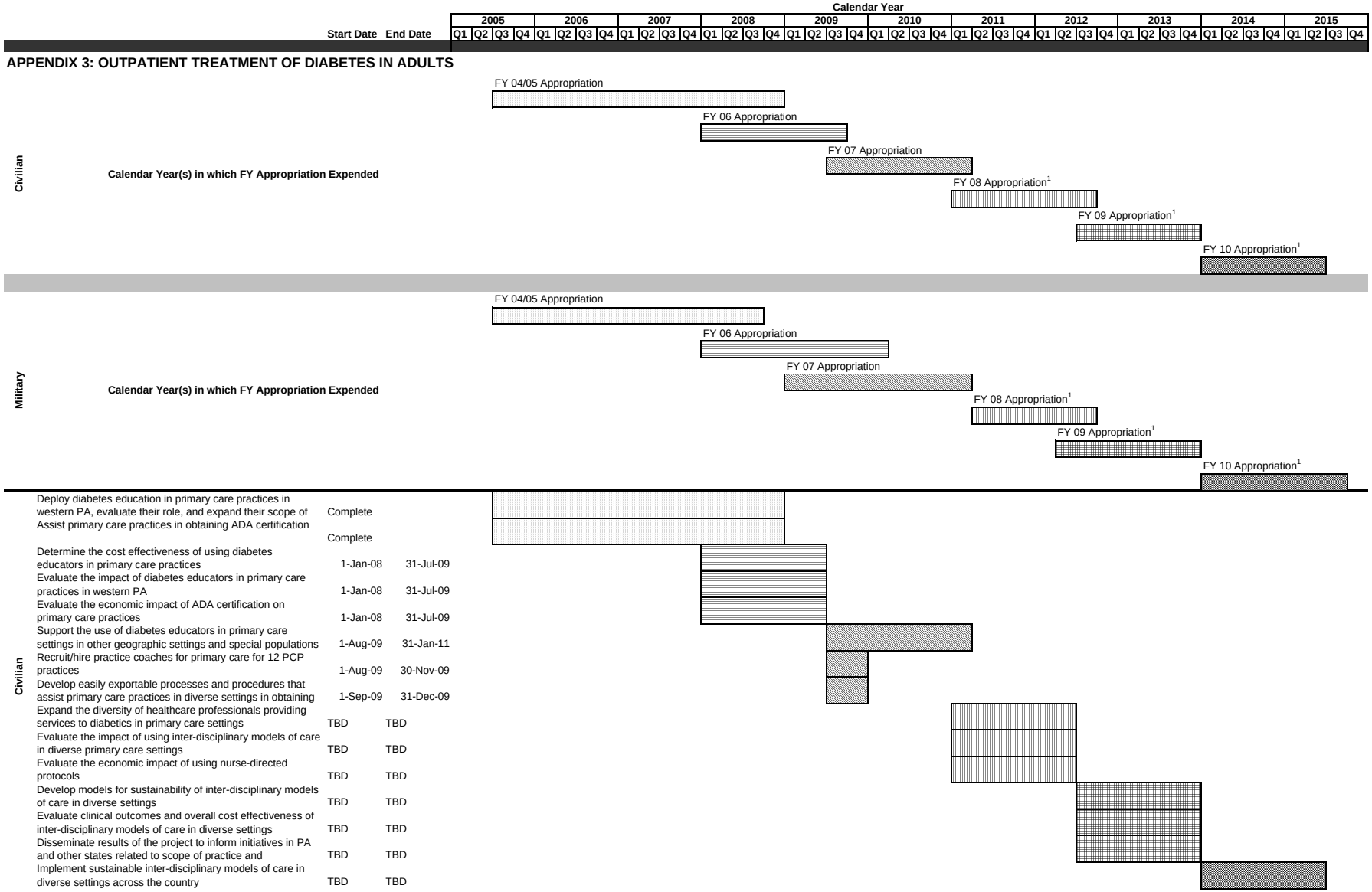

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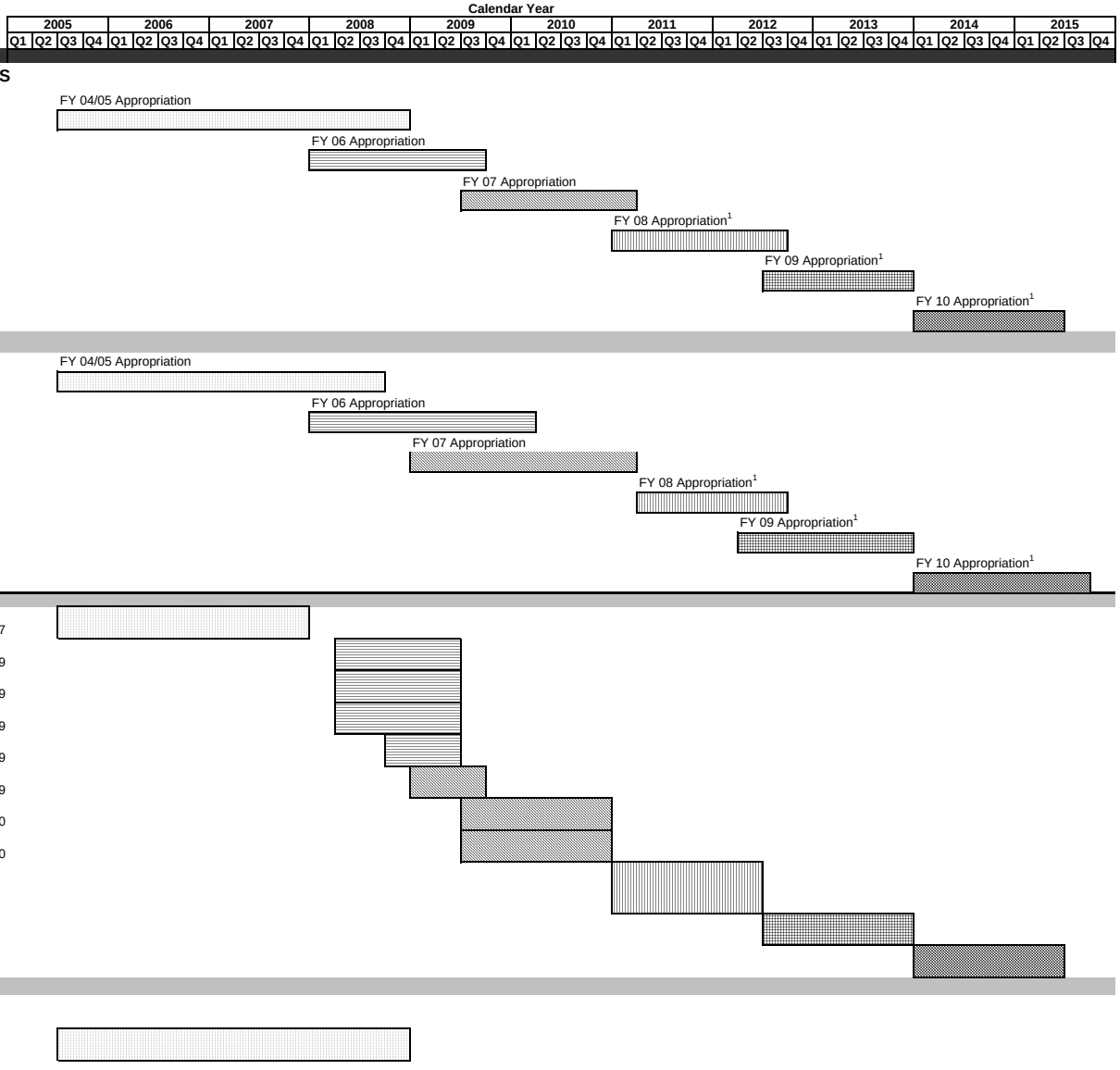

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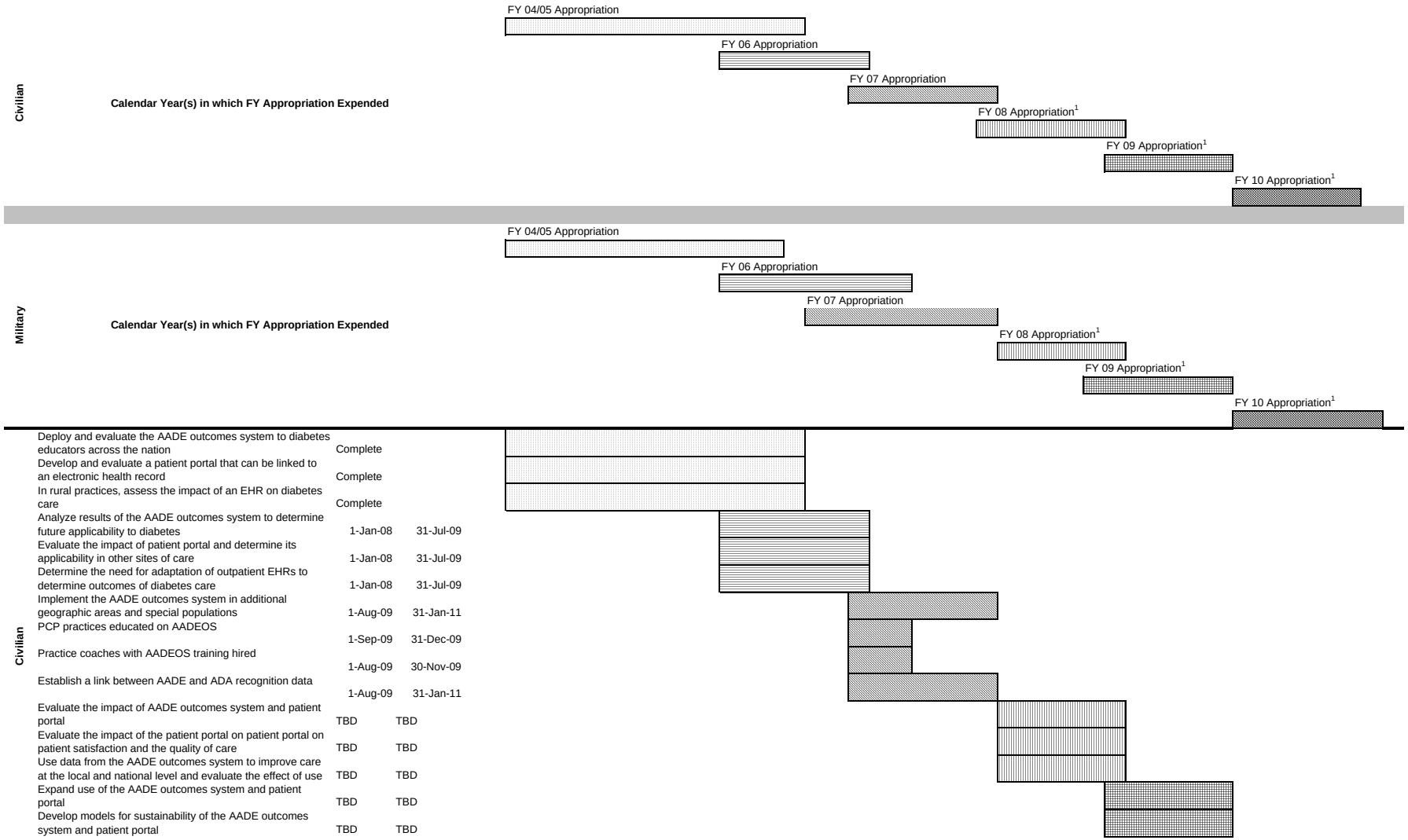

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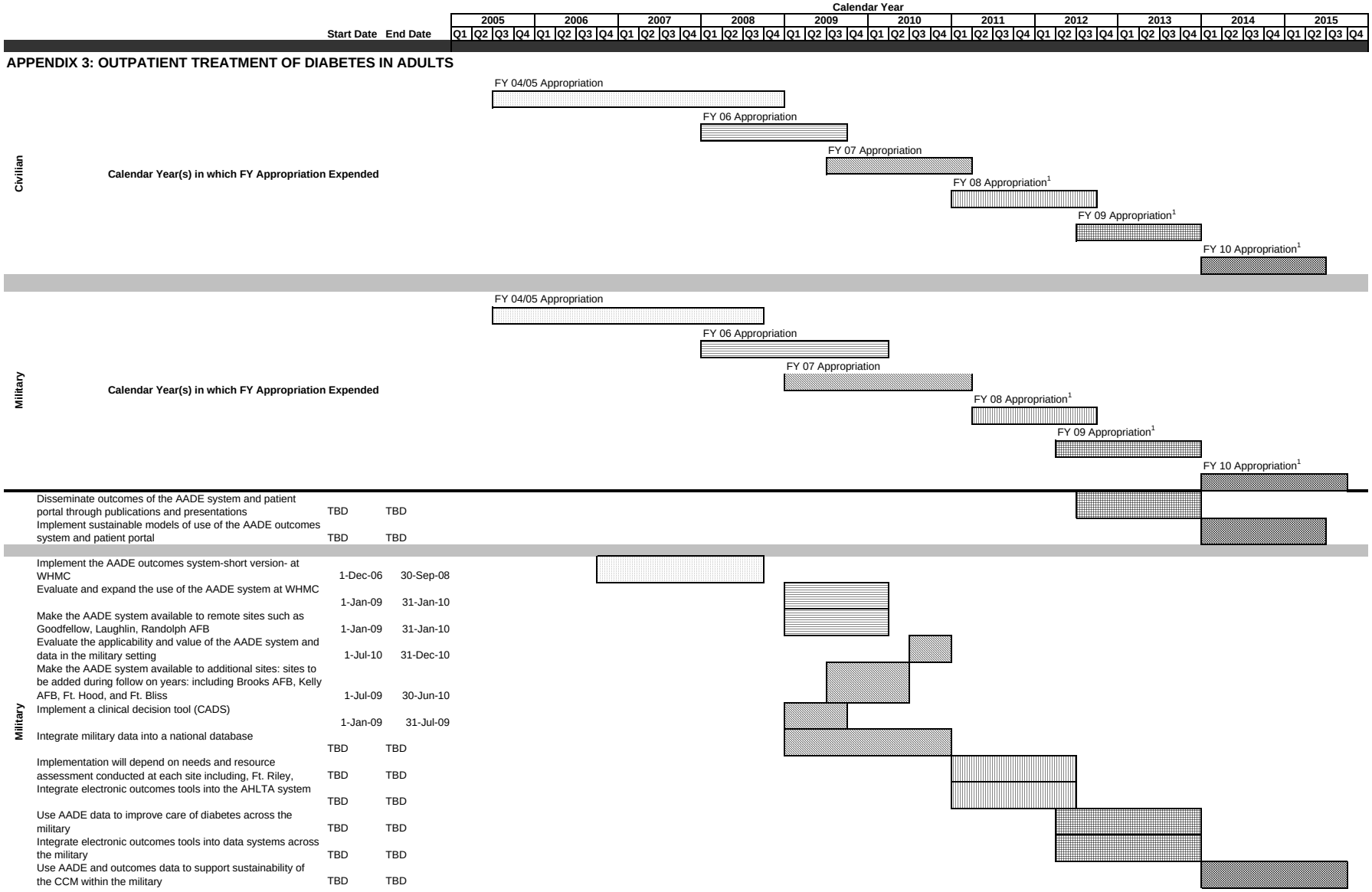

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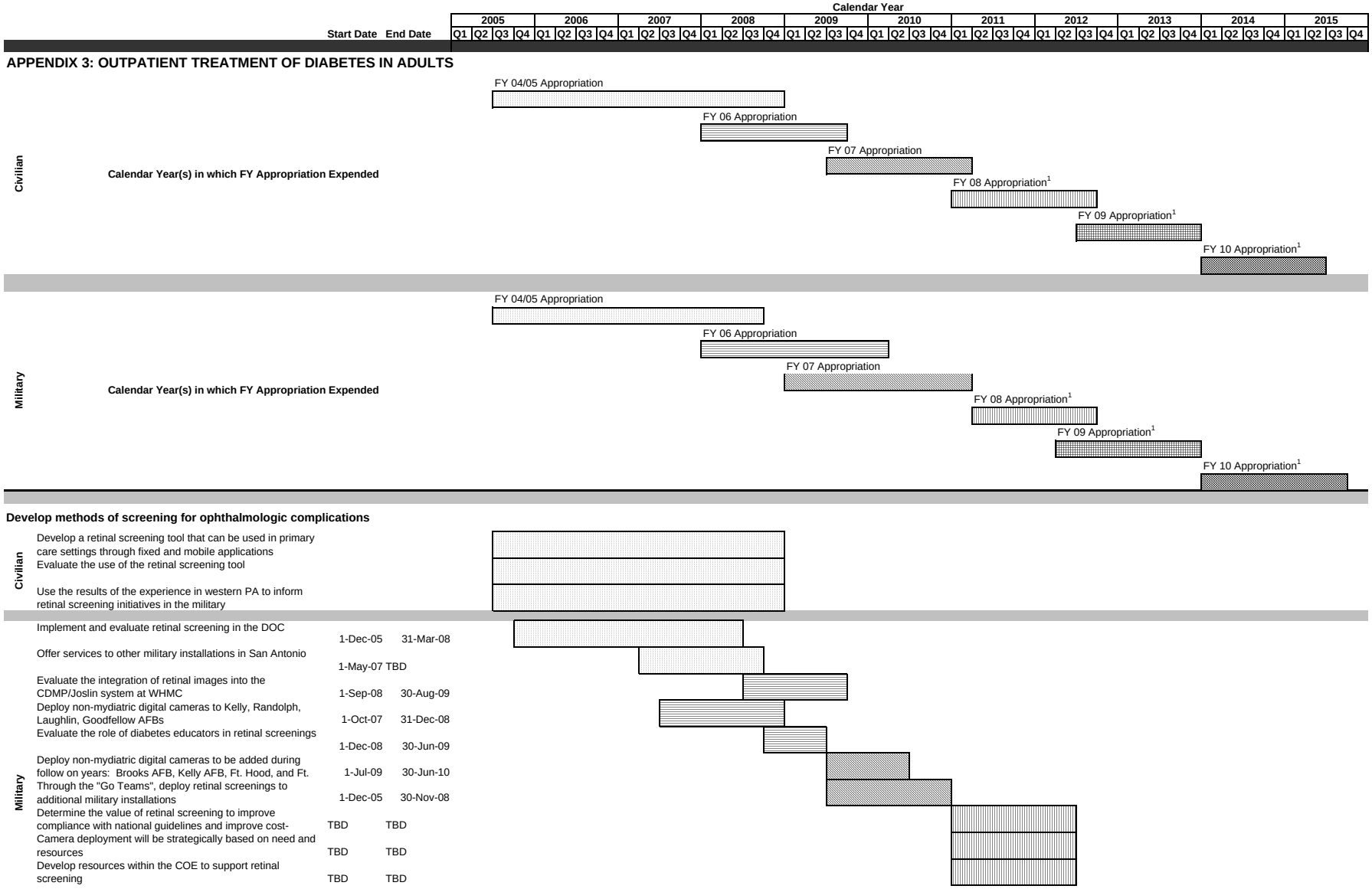
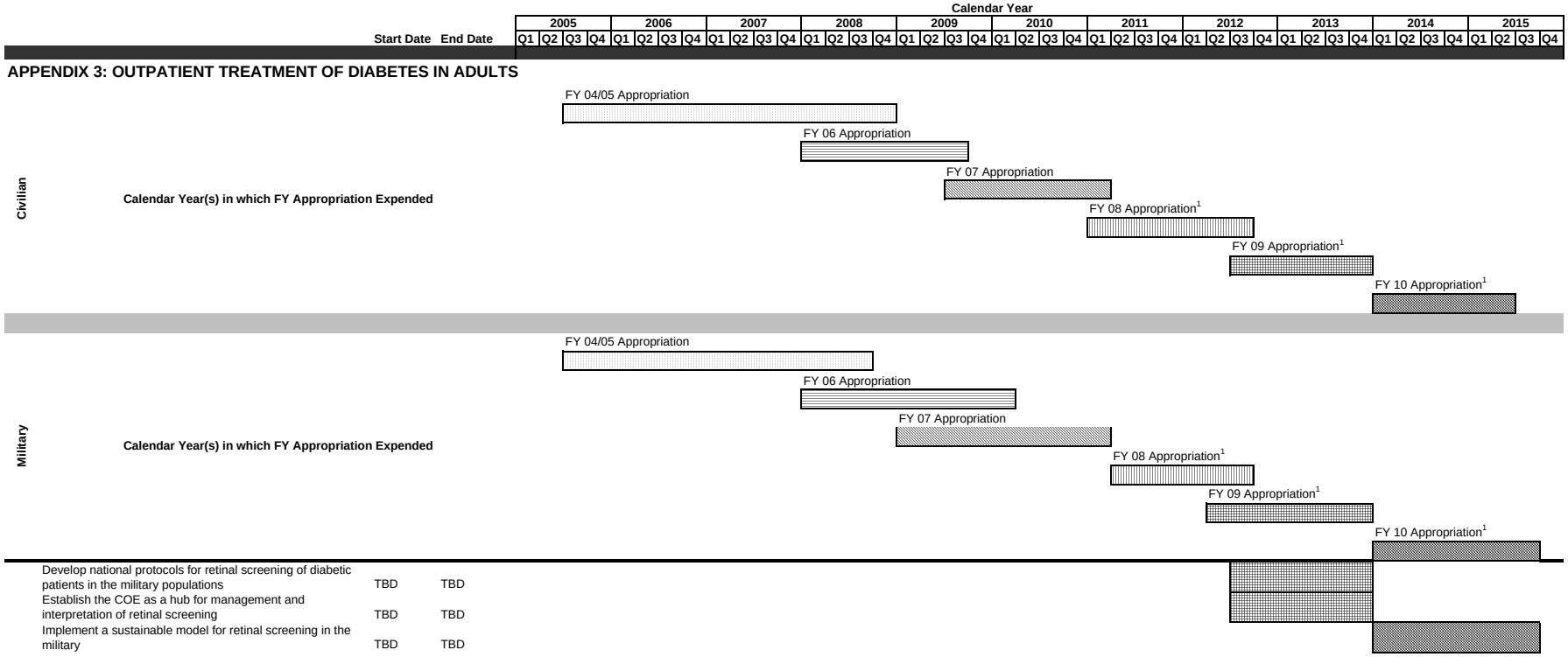


UPMC

University of Pittsburgh Diabetes Institute

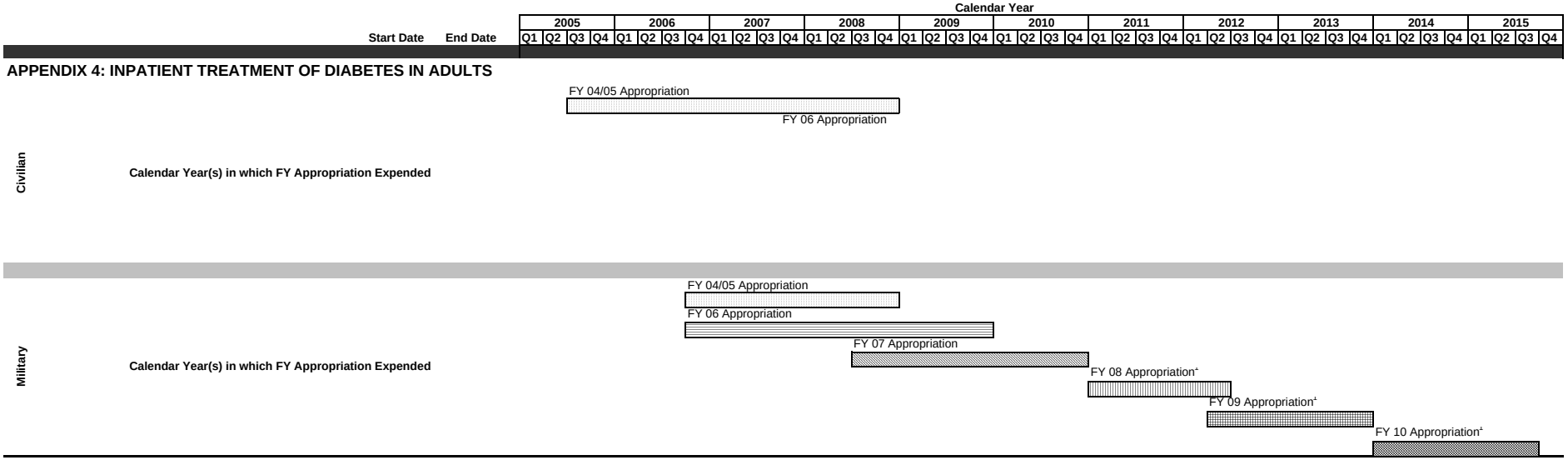
APPENDIX 3: OUTPATIENT TREATMENT OF DIABETES IN ADULTS



Develop national protocols for retinal screening of diabetic patients in the military populations	TBD	TBD
Establish the COE as a hub for management and interpretation of retinal screening	TBD	TBD
Implement a sustainable model for retinal screening in the military	TBD	TBD

[1]Definitive Dates for each technical objective have not yet been determined for FY08, FY09, or FY10 funding. Shading is representative of expected Period of Performance

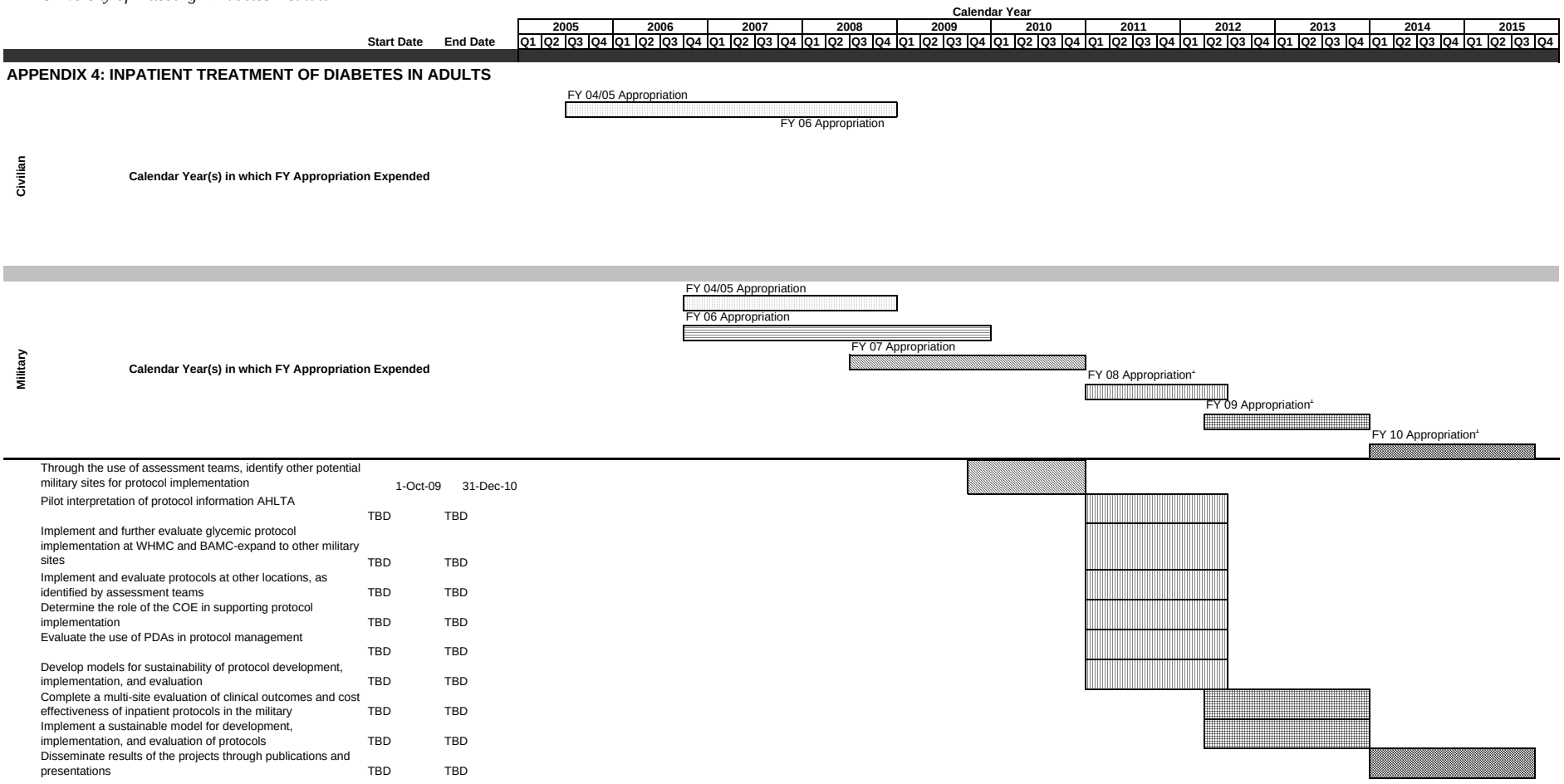
APPENDIX 4: INPATIENT TREATMENT OF DIABETES IN ADULTS



Develop and Deploy inpatient glycemic management

Civilian	Develop glycemic management protocols	Complete	
	Deploy glycemic management protocols in UPMC tertiary facilities	Complete	
	Evaluate the clinical effectiveness and cost-effectiveness of selected protocols	Complete	
Military	Review Protocols developed at UPMC and determine applicability to WHMC	2-Oct-06	31-Aug-08
	Engage staff to support inpatient protocol implementation	1-Nov-06	31-Dec-08
	Deploy selected protocols	1-Aug-07	31-Dec-08
	Begin to evaluate clinical impact of protocols	1-Aug-07	31-Jul-09
	Implement insulin drip protocol	2-Oct-06	31-Jul-08
	Insulin Pen Delivery System Study	08-Jul	09-Dec
	Implement additional protocols (Hypoglycemic protocol, transition from IUV to subcutaneous insulin, standardized physician order sets for subcutaneous insulin, insulin pen delivery system study)	1-Aug-08	30-Aug-09
	Develop a model for determining the cost effectiveness of protocol implementation in military settings	1-Sep-08	30-Aug-09
	Evaluate capabilities, required steps and schedules for incorporating protocols into electronic health record	1-Sep-08	30-Aug-09
	Implement additional Hypoglycemic protocol	1-Sep-09	30-Aug-10
	Continue to implement protocols and investigate/evaluate effectiveness	1-Oct-08	31-Oct-10
	Review model and recommend implementation plan	1-May-09	31-May-10
	Perform a rigorous study to evaluate the impact of implementing the hypoglycemia protocol and submit report	1-Sep-08	28-Feb-10
	Determine the feasibility and benefits of establishing glycemic management teams in military inpatient facilities	1-Sep-08	31-Oct-09

APPENDIX 4: INPATIENT TREATMENT OF DIABETES IN ADULTS



[1]Definitive Dates for each technical objective have not yet been determined for FY08, FY09, or FY10 funding. Shading is representative of expected Period of Performance

2006 Department of Defense Appropriations Funding

Submission for projects at the University of Pittsburgh Medical Center in Pittsburgh and at Wilford Hall Medical Center in San Antonio

ROUGH ORDER OF MAGNITUDE (ROM) ANALYSIS

MILITARY

GOALS	FOCUS AREA	DIRECTS	% OF TOTAL	ALLOCATED MILITARY ONLY ADMIN AND RESEARCH COSTS	MILITARY DIRECTS BEFORE NORTH ALLOCATION	% OF OVERALL TOTAL	ALLOCATED ADMINISTRATIVE AND RESEARCH COSTS - NORTH	TOTAL DIRECTS	INDIRECTS	TOTAL
2,6	Pediatrics	300,451	14.97%	88,087	388,538	3.93%	82,075	470,614	20,260	**490,874**
3	Primary Prevention	186,659	9.30%	54,726	241,385	2.44%	50,990	292,375	55,519	**347,894**
4	Outpatient	1,304,875	65.02%	382,568	1,687,443	17.05%	356,457	2,043,900	388,112	**2,432,012**
5	Inpatient	214,909	10.71%	63,008	277,917	2.81%	58,707	336,625	63,921	**400,546**
Sub-Total Military		**2,006,895**	**100.00%**	**588,389**	**2,595,284**	**26.22%**	**548,230**	**3,143,514**	**527,811**	**3,671,325**

NORTH

GOALS	FOCUS AREA	DIRECTS	DIRECTS BEFORE NORTH ALLOCATION	% OF OVERALL TOTAL	ALLOCATED ADMINISTRATIVE AND RESEARCH COSTS - NORTH	TOTAL DIRECTS	INDIRECTS	TOTAL
2,6	Pediatrics	1,888,535	1,888,535	19.08%	398,936	2,287,471	280,344	**2,567,815**
3	Primary Prevention	1,229,943	1,229,943	12.43%	259,814	1,489,757	390,374	**1,880,131**
4	Outpatient	4,050,390	4,050,390	40.92%	855,608	4,905,998	1,285,561	**6,191,559**
5	Inpatient	134,057	134,057	1.35%	28,318	162,375	42,549	**204,924**
Sub-Total North		**7,302,925**	**7,302,925**	**73.78%**	**1,542,676**	**8,845,601**	**1,998,827**	**10,844,428**

Total Budget	9,309,820	588,389	9,898,209	100.00%	2,090,906	11,989,115	2,526,638	**14,515,754**

2007 Department of Defense Appropriations Funding

Submission for projects at the University of Pittsburgh Medical Center in Pittsburgh and at Wilford Hall Medical Center in San Antonio

ROUGH ORDER OF MAGNITUDE (ROM) ANALYSIS

MILITARY

GOALS	FOCUS AREA	DIRECTS	% OF TOTAL	ALLOCATED MILITARY ONLY ADMIN AND RESEARCH COSTS	MILITARY DIRECTS BEFORE NORTH ALLOCATION	% OF OVERALL TOTAL	ALLOCATED ADMINISTRATIVE AND RESEARCH COSTS - NORTH	TOTAL DIRECTS	INDIRECTS	TOTAL
2,6	Pediatrics	375,254	17.89%	127,703	502,957	4.65%	93,157	596,114	115,680	**711,795**
3	Primary Prevention	255,069	12.16%	86,803	341,873	3.16%	63,321	405,194	64,141	**469,334**
4	Outpatient	1,434,277	68.38%	488,101	1,922,378	17.78%	356,060	2,278,438	442,147	**2,720,585**
5	Inpatient	32,907	1.57%	11,199	44,106	0.41%	8,169	52,275	10,144	**62,420**
Sub-Total Military		**2,097,508**	**100.00%**	**713,806**	**2,811,314**	**26.00%**	**520,708**	**3,332,021**	**632,112**	**3,964,134**

NORTH

GOALS	FOCUS AREA	DIRECTS		DIRECTS BEFORE NORTH ALLOCATION	% OF OVERALL TOTAL	ALLOCATED ADMINISTRATIVE AND RESEARCH COSTS - NORTH	TOTAL DIRECTS	INDIRECTS	TOTAL
2,6	Pediatrics	2,171,535		2,171,535	20.08%	402,209	2,573,744	181,069	**2,754,813**
3	Primary Prevention	3,269,120		3,269,120	30.23%	605,502	3,874,622	986,721	**4,861,343**
4	Outpatient	2,543,598		2,543,598	23.52%	471,122	3,014,719	767,736	**3,782,455**
5	Inpatient	18,328		18,328	0.17%	3,395	21,723	5,532	**27,255**
Sub-Total North		**8,002,581**		**8,002,581**	**74.00%**	**1,482,227**	**9,484,808**	**1,941,058**	**11,425,866**

Total Budget	10,100,089	713,806	10,813,895	100.00%	2,002,935	12,816,829	2,573,170	**15,390,000**

Appendix B. List of Personnel

LIST OF PERSONNEL

Diabetes Prevention and Treatment Programs

University of Pittsburgh Medical Center

Principal Investigator: Barbara Barnes, MD

2006 Department of Defense Appropriations Funding: W81XWH-07-2-0080

Barnes	Barbara	Principal Investigator	UPMC Adult
Beltz	Kathleen	Admin Coordinator	UPMC Adult
Bickus	Joseph	Financial Analyst Senior	UPMC Adult
DiNardo	Monica	Diabetes Project Manager	UPMC Adult
Dunn	Michael	Medical Military Liaison	UPMC Adult
Duty	Darrell	IT Manager	UPMC Adult
Elliot	Soni	Diabetes Research Coordinator	UPMC Adult
Emerson	Sharlene	Dir. Outpatient Ed	UPMC Adult
Esherick	Angela	Dietitian	UPMC Adult
Fiorillo	Anthony	Subject Matter Expert	UPMC Adult
Faderewski	Michelle	Director Marketing Communications	UPMC Adult
Francus	Kimberly	Grants Specialist II	UPMC Adult
Gorring	Karen	Admin. Assistant	UPMC Adult
Hutter	Kelsey	Preventionist	UPMC Adult
Jindra	Mary Jo	Admin Program Manager	UPMC Adult
Johnson	Patricia	Diabetes Educator	UPMC Adult
Kanter	Justin	Accountant Associate	UPMC Adult
Kudra	Leslie	IT Project Manager	UPMC Adult
Lee	Rhonda	Lay Health Coach	UPMC Adult
Ling	Luke	Webmaster	UPMC Adult
Love	Kim	Admin Program Manager	UPMC Adult
Leader	Susan	Program Director	UPMC Adult
McWilliams	Janis	Diabetes, Pgm.Mgr	UPMC Adult
Misiak	Michelle	Manager, Finance	UPMC Adult
Oates	Bethany	Senior Accountant	UPMC Adult
Piatt	Gretchen	Epidemiologist	UPMC Adult
Powell	Robert	Program Manager	UPMC Adult
Sakson	Suzanne	Program Director	UPMC Adult
Seidel	Miriam	Diabetes Project Manager	UPMC Adult
Smalley	Denise	Senior Financial Analyst	UPMC Adult
Thearle	Margaret	Diabetes Project Manager	UPMC Adult
Tilves	Debra	Regulatory Coordinator	UPMC Adult
Tomasic	Helen	Lay Health Coach	UPMC Adult
Valen	Lindsey	Manager, Media Relations	UPMC Adult
Warner	Carol	Diabetes Prev. Ed. Specialist	UPMC Adult

Alexander	Jamie	Scheduler (Sec II)	UPMC Pediatrics
Arslanian (KEY)	Silva	Investigator	UPMC Pediatrics
Bacha	Fida	Endocrinologist	UPMC Pediatrics
Bednarz	Lori	Certified Diabetes Educator	UPMC Pediatrics
Bray	Maggie	Web site development	UPMC Pediatrics
Burkhart	Shelly	Sec II	UPMC Pediatrics
Burns	Stephen	Research Post Doc	UPMC Pediatrics
Chidron	Deborah	Admin Asst II	UPMC Pediatrics
Detwiler	Lindsey	Dietitian, Generalist	UPMC Pediatrics
Drnach	Michael	Admin. Director	UPMC Pediatrics
Ellis	Demitrius	Professor of Pediatrics	UPMC Pediatrics
Fitzgerald	Douglas	Data Analyst	UPMC Pediatrics
Guerra	Nancy	CRNP	UPMC Pediatrics
Hallak	Souheil	Database Coordinator	UPMC Pediatrics
Hannon	Tamaron	Endocrinologist	UPMC Pediatrics
Hurley	Katherine	Community Coordinator	UPMC Pediatrics
Kolls	Jay	Professor of Pediatrics	UPMC Pediatrics
Krall	Jodi	Diabetes Project Manager Pediatrics	UPMC Pediatrics
Kuchera	Anne Marie	Behavior Therapist	UPMC Pediatrics
Lee	So Jung	Clinical Scientist	UPMC Pediatrics
Libman	Ingrid	Endocrinologist	UPMC Pediatrics
Lowe	Mark	Professor of Pediatrics	UPMC Pediatrics
Marcus	Marsha	Assoc Prof of Psychiatry	UPMC Pediatrics
Marshall	Pamela	Program Coordinator	UPMC Pediatrics
McDowell	Katie Anne	Lab Research Tech II	UPMC Pediatrics
McQuade	Megan	Dietitian, Generalist	UPMC Pediatrics
Moorefield	Ebony	Program Coordinator, CRNP	UPMC Pediatrics
Nicholls	Robert	Director, CHP	UPMC Pediatrics
Nucci	Anita	Nutritional Supervisor	UPMC Pediatrics
Paris	Marguerite	Dietitian, Generalist	UPMC Pediatrics
Parisi	Sara	Dietitian, Generalist	UPMC Pediatrics
Perrott	Nancy	Dietitian, Generalist	UPMC Pediatrics
Prince	Allison	Research Coordinator	UPMC Pediatrics
Rao	Goutham	Clinical Director	UPMC Pediatrics
Rofey	Dana	Behavioral Scientist	UPMC Pediatrics
Sciulli	Leicia	PIC	UPMC Pediatrics
Trucco	Massimo	Professor of Immunology	UPMC Pediatrics
Vincent	Angela	Behavior Therapist	UPMC Pediatrics
Vincent	Angela	Behavior Therapist (coverage A. Kuchera)	UPMC Pediatrics
Warren	Carla	Medical Asst.	UPMC Pediatrics
Weidinger	John	Physician Extender	UPMC Pediatrics

Weisbrod	Vanessa	Wellness Program Spec	UPMC Pediatrics
Baquero, MD	Jeannie	Endocrinologist	UPMC WHMC
Bennett	Petra	Outpatient Nurse	UPMC WHMC
Callahan	Fahiman	Dietitian	UPMC WHMC
Caywood	Louann	Retinal Screener/Admin	UPMC WHMC
Choudary	Ahsan	Research Asst-IP	UPMC WHMC
Crail	Tanya	Admin Clinic Mgr/Diabetes Administrator	UPMC WHMC
Fencik	Amber	Medical Assistant	UPMC WHMC
Galindo	Ray	Medical Receptionist	UPMC WHMC
Garcia	Tricia	Research Asst	UPMC WHMC
Garwood	Pam	CRNP-Primary Care Srvs	UPMC WHMC
Gonzalez	Dorothy	Diabetes Educator	UPMC WHMC
Hernandez	Lisa	Medical Secretary II-Promotion (Replaces Retinal Screen/Admin Above)	UPMC WHMC
Holtz	Claudia	Diab Prev Ed Specialist	UPMC WHMC
Hultquist	Timothy	LPN - Go Team	UPMC WHMC
Kelley	Beverly	Diabetes Educator - Go Team	UPMC WHMC
Mangra	Nadira	CRNP - Pediatrics	UPMC WHMC
Martinez	Athena	Diab Prev Ed Specialist	UPMC WHMC
Morales	Yvonne	Medical Assistant	UPMC WHMC
Naff	Paula	Diabetes Educator - Go Team	UPMC WHMC
Perez	Jose	Systems Analyst Intermed. (Replaces Data Analyst Above)	UPMC WHMC
Poenish	Karen	Pediatric Project Manager	UPMC WHMC
Pollard	Joseph	Clinical Research Coor	UPMC WHMC
Ramirez	Ernestina	LPN	UPMC WHMC
Ramirez	Jose	LPN	UPMC WHMC
Rijos	Lexa	Diabetes Educator-IP	UPMC WHMC
Rogiers	Rayna	Dietitian Generalist	UPMC WHMC
Salazar	Estella	CRNP	UPMC WHMC
Sauvage	Mechelle	Administrative Coordinator	UPMC WHMC
Scribbick	Frank	Ophthalmologist	UPMC WHMC
Silguero	Marina	Regulatory Affairs Coord	UPMC WHMC
Slattery	Bridget	CRNP - DCOE	UPMC WHMC
Stapley, PhD	Jonathan	Diabetes Administrator	UPMC WHMC
Stumbaugh	Yolanda	Optha Tech	UPMC WHMC
Terry	Sherri	Patient Care Tech	UPMC WHMC
Wallace	Brooke	Behavioral Therapist	UPMC WHMC
Waller, MD	Stephen	Ophthalmologist	UPMC WHMC
Ward	Stacey	Diabetes Educ (Inpat)	UPMC WHMC
Welz	Trina	Psychologist	UPMC WHMC
Wolf	Donna	WHMC Research Director	UPMC WHMC

Appendix C. Planning Conference Summary

Planning Conference – Working Toward a National Model for Diabetes
Monday, August 31, 2009 - University Club, Pittsburgh, Pa

National Associations and Institutions
*Ann Albright, PhD, Director, Division of Diabetes Translation, CDC
Patrick Alwine, Office of Congressman Murtha
Robert Gabbay, MD,PhD (via call), Dir, Penn State Hershey Instit. for Diabetes/Obesity
Russell Glasgow, PhD, Institute for Health Research, Kaiser Permanente Colorado
Elizabeth Holmes, President & CEO, Theranos, Inc.
*Christine Hunter, PhD, USPHS, Director of Behavioral Research, NIDDK
*David Klonoff, MD, FACP, Clinical Prof. of Med., UCSF, Editor, Journal of Diabetes Techn.
*Philip Magistro, Deputy Director, Program Implementation, Office of Health Care Reform
Sue McLaughlin, RD, CDE, President, Healthcare and Education, ADA
Charles Peterson, MD, Chief Scientist, TATRC
Paul Robertson, MD, President, Medicine and Science, ADA
*Mark True, MD, LT COL, Director, Diabetes Center of Excellence, Lackland AFB
*Robert Vigersky, MD, COL MC, Director, Diabetes Institute, Walter Reed

UPMC
*Barbara Barnes, MD, MS, VP, Sponsored Programs, Research Support and CME
*Robert DeMichiei, SVP and CFO
Michael Drnach, MBA, Executive Director, Ambulatory Services, CHP
Susan McDermot Leader, CPA, Administrative Director, Diabetes Institute
Christopher Maley, Executive Administrator, CHP
*Goutham Rao, MD, Clinical Director, Weight Management and Wellness Center, CHP
*Dana Rofey, PhD, Assistant Professor, Pediatrics and Psychiatry, CHP

University of Pittsburgh
*Michael Dunn, MD, FACP, (Ret Gen) Clinical Prof. Med./Biomed. Informatics,
Associate Chief for Translational Research
Trevor Orchard, MD, MMedSci, FAHA, Interim Chair, Dept. of Epid., Prof. of Epid., Med. and Ped.
Gretchen Piatt, MPH, PhD, Associate Director of Evaluation, Diabetes Institute
*Linda Siminerio, RN, PhD, Executive Director, Diabetes Institute
*Andrew Stewart, MD, Chief, Division of Endocrinology and Metabolism, Professor of Medicine
*Janice Zgibor, PhD, Director of Data Evaluation, Diabetes Institute

Observers:
George Huber, JD, Associate Dean for Public Policy, Prof. of Public Health Practice, Pitt, GSPH
Jodi Krall, PhD, Project Manager, CHP
Andrea Kriska, PhD, Associate Professor, Department of Epidemiology, Pitt, GSPH
Ellen Mazo, Director, Government Affairs, CHP
Rebecca Middleton, The Rhoads Group
Tatia O'Connor, Senior Manager, Corporate and Special Events, UPMC
Megan Grote Quantrini, Manager, Media Relations, UPMC
Robert Read, Vision Portfolio Manager and IPA, TATRC
David Russell, Director, Strategic Planning, UPMC
Eugenia Stoner, Government Relations, Pitt
Valerie Trott, Executive Administrator, Pitt

Elizabeth Venditti, PhD, Assistant Professor of Psychiatry, Pitt
***Presenters**

Mr. Rob DeMichiei and Dr. Barbara Barnes	Welcome – Diabetes and UPMC
Dr. Andrew Stewart	Diabetes Research at University of Pittsburgh
Dr. Linda Siminerio and Dr. Michael Dunn	University of Pittsburgh Diabetes DOD Program Overview
Mr. Philip Magistro	PA Chronic Care Commission
Dr. Janice Zgibor	Chronic Care Model/Cost Effectiveness
Dr. Gautham Rao and Dr. Dana Rofey	Pediatric Obesity
Lt. Col. Mark True	USAF Diabetes Research Program at Wilford Hall Medical Center
Dr. Robert Vigersky	US Army Research Program at Walter Reed Medical Center
Dr. Ann Albright	Diabetes as a Public Health Epidemic in the U.S. (CDC)
Dr. Christine Hunter	US Research in Diabetes (NIDDK)
Dr. David Klonoff	Diabetes Technology

Afternoon Discussion – Planning the Future for Diabetes Projects and Collaborations

Introduction

Dr. Siminerio opened the afternoon discussion with the following objectives:
To discuss areas of study presented at morning session
To determine areas for future study
To find areas for collaboration

Discussion topics and summaries:

Information Technology (IT) Systems

Dr. Michael Dunn reviewed the challenges of disparate government and commercial health information systems that prevent effective coordination and assessment of chronic care for persons with diabetes. He presented opportunities to develop patient controlled personal health records (PHR) linked to advanced chronic care tools. He noted promising government initiatives to partner with commercial patient controlled data stores available from Google or Microsoft. The concept would offer a competitive environment and systems that already enjoy consumer trust, using the connectivity tools of the new National Health Information Network (NHIN) to overcome present interoperability barriers.

Dr. Robert Vigersky is currently implementing a PHR project with commercial vendors. He stated that the military DIACAP system security process would be needed to prove the applications are secure if used in military IT systems. This process is complex and could present a barrier to implementation. Dr. Mark True asked who directs IT policy in the military.

Dr. Dunn stated that it is overseen by several panels and sometimes paralysis is created.

Dr. True requested that IT projects be implemented that provide decision support tools for busy diabetes practitioners. Projects like the Computer Assisted Decision Support (CADS), currently being tested, continue to be considered for future funding.

Dr. Paul Robertson stated that all organizations should work together on the type 2 diabetes (T2D) problem since T2D is a syndrome that needs to be studied in diverse populations. Dr. Albright acknowledged that most people and systems are unwilling to share data. Dr. Orchard responded that there is an enormous potential if all data sets/systems are brought together. Dr. Vigersky stated that we should leverage this consortium to inform health care decisions.

Several members noted an enormous opportunity for those representing national diabetes organizations and institutions to develop a joint statement regarding information systems and diabetes management. Dr. Robertson and Ms. Sue McLauglin reported that they will present this to the ADA Executive Board at their upcoming meeting.

Bio-Marker / Risk Assessment Technology

Elizabeth Holmes described the *Theranos* biomarker technology developed to identify people at risk and guide treatment choices for various disease states. There was discussion regarding how the technology could be used to provide detection of diabetes and lifestyle interventions for military and civilian populations. Ms. Holmes stated that she would like to test the technology in a PRIDE community. Dr. Albright raised concerns that the biomarker technology could be expensive and ineffective in communities where basic chronic care is unavailable. Dr. Vigersky supported the need to test this type of technology and expressed interest in further testing in military settings, like the Walter Reed Diabetes Institute. Dr. Siminerio suggested that perhaps a pilot study in a selected PRIDE community could provide insight into risk identification technology in a civilian community.

Military Issues

Dr. Zgibor asked if resources in the military are lacking. Dr. Vigersky stated that the military is very different than many civilian community areas. Dr. Dunn stated that military personnel "get it".

Dr True added that there is a shortage of specialists, like endocrinologists, diabetes educators and other resources. Dr. Siminerio agreed that the military outreach bases resemble rural and underserved community sites with significant resource shortages. Several members of the group decided that there is not one answer that will fit both community and military needs. Both just "don't have enough personnel and resources" to take care of needs.

Primary Prevention

Dr. Albright reiterated the need for primary prevention of diabetes and cardiovascular disease (CVD). With the shortage of resources, programs need to consider providing primary prevention beyond the medical/clinical environment to community settings. Communicating risk to populations and training individuals to provide evidence-based prevention efforts is critically important for both children and adults. Dr. Orchard posed the development of a national prevention center to provide prevention services for civilian and military populations.

Deploying the Chronic Care Model

Dr. Siminerio referred to the work currently being done in the Pittsburgh Regional Initiative on Diabetes Education (PRIDE) communities and similar efforts being done using the Chronic Care Model (CCM) by the PA Chronic Care Commission across the Commonwealth. She asked if the CCM should continue to be used as the framework for the study of health care delivery to inform chronic disease management for the nation. Dr. Janice Zgibor stated that her team has conducted 10 focus groups and found that the providers in the PRIDE communities are severely resourced and personnel strapped. They request immediate access to services, like diabetes education.

Dr. Hunter acknowledged that many primary care providers do not know how to manage multiple chronic diseases and that delivery systems need to attend to this challenge. Dr. Russell Glasgow stated that community resources are considered to be a critically important element of the CCM and need to be further studied along with health disparities and inequities.

Self-Management Systems

Ms. Sue McLaughlin stated that a national tool is needed to collect data on self-management and education practices. This is critically important for informing decisions for Medicare and insurers for proper reimbursement. Dr. Hunter stated that Native American populations are being studied, and other populations and areas like depression and self-management need further investigation. Dr. Klonoff referred to diabetes management areas like self-monitoring of blood glucose (SMBG) that need to be studied in many populations. He referred to a publication identifying the need for people to learn how to interpret SMBG results. Ms. McLauglin concurred and said that a patient-driven data base could be a rich resource to monitor and address these questions. Dr. Siminerio suggested that questions related to behavior, like monitoring and medication adherence, could be embedded into a national database representing many diverse populations.

Conclusions

Dr. Vigersky stated that currently there is no formal mechanism to identify projects and priorities and an infrastructure to determine areas for study would be useful. Dr. Stewart added that a rigorous peer review process be employed for all proposals. Dr. Barbara Barnes asked that any future funding hosted by UPMC/Pitt should be collaborative and multi-institutional research.

There are many program elements in both diabetes prevention and treatment that require investigation. Pittsburgh and the region serve as an excellent forum to continue diabetes translational research efforts with its experienced diabetes academic team, the UPMC clinical setting linking to disparate 'underserved communities. UPMC and the University should focus on DOD projects with assistance from government partners.

Areas for future study/discussion:

- Primary prevention of T2D and CVD (A National Prevention Center)
- Assessing risk with bio-markers
- Communicating risk and training programs in diverse communities
- Information technology – linking systems with PHRS
- Telemedicine approaches
- Decision support tools
- Models of health care delivery (community and cost effectiveness evaluation)
- Self-management /Behavioral/Psychosocial themes
- Health care disparities
- Basic science

It was agreed that a steering committee be established. Dr. Barnes stated that the first task should be to look at the current AF strategic plan and formulate ideas for the '09 funding. The steering committee should convene in November or earlier. Proposed members are as follows:

David Klonoff, MD Diabetes Technology
Trevor Orchard, MD U Pitt Graduate School of Public Health
Charles Peterson, MD TATRC
Goutham Rao, MD Children's Hospital
Paul Robertson, MD ADA
Linda Siminerio, PhD U Pitt Medicine/Nursing
Mark True, Lt Col, MD AF WHMC
Robert Vigersky, Col, MD Army WRMC
TBN SGR representative